The Columbia

# SCIENCE AND TECHNOLOGY LAW REVIEW

www.stlr.org

# RESEARCH FRAUD: METHODS FOR DEALING WITH AN ISSUE THAT NEGATIVELY IMPACTS SOCIETY'S VIEW OF SCIENCE

### Dr. Dov Greenbaum<sup>1</sup>

Like the legal and medical professions, the relatively insular academic scientific community has always preferred to deal with instances of misconduct quietly, without external intervention. Recent highly publicized instances of scientific misconduct have shocked the community, renewing calls for alternative approaches to address this growing threat to science's position of trust within society, and consequently the public's generous funding of academic research. Science's inability to effectively define the outer boundaries of misconduct, coupled with a lack of ethics education and enforcement, has led to the current situation. This article examines the current level of fraud and enforcement and suggests some policy alternatives to the status quo.

This article first presents a novel tiered structure based on a simple analysis of two basic components of any instance of scientific misconduct, to provide a method to discriminate between different levels of misconduct. Next, this article looks to a number of authorities and institutions that could educate current and future scientists about the nature and effects of fraud in scientific research. Finally, this article explores options for enforcing and punishing instances of misconduct, including both civil and criminal, particularly mindful of the devastating career

Thank you to Society in Science: The Branco Weiss Fellowship, Eidgenössische Technische Hochschule (ETH) Zürich, for financial support.

<sup>&</sup>lt;sup>1</sup>Postdoctoral Fellow, Center for Law and the Biosciences, Stanford Law School, Stanford University; JD, Berkeley Law, University of California (Boalt Hall); MPhil, Genetics Yale University, PhD, Genetics/Bioinformatics, Yale University.

Thank you to Professors Hank Greely and Pilar Ossorio for their help and comments.

Available at <a href="http://www.stlr.org/cite.cgi?volume=10&article=2">http://www.stlr.org/cite.cgi?volume=10&article=2</a>

implications resulting from any association with an investigation of misconduct. In this vein, First Amendment and due process issues are highlighted and examined. This article concludes that, given the devastating repercussions to even exonerated scientists, a criminal code that takes into account the particular concerns of the scientific community would best provide protection for scientists and promote a more ethical scientific community.

#### I. INTRODUCTION

Trust and integrity have always been central components of the basic science research enterprise. For centuries scientists have successfully policed themselves, preserving their communal values. While seventeenth century mechanisms, created and imposed by the emerging scientific community, used to adequately regulate the profession,<sup>2</sup> the tremendous growth and expansion of science, particularly within the last half century,<sup>3</sup> has made self-regulation of scientific conduct significantly more difficult and complex.<sup>4</sup> Some, asserting that science has lost its moral compass, are attempting to create and impose artificial boundaries to prevent unethical practices, placing unhelpful limitations on scientific discovery. One such boundary commonly suggested, but nearly impossible to uphold, has been that basic researchers limit themselves to only those research directions that will categorically never harm humanity.<sup>5</sup>

3

. . . .

Science . . . has gone from being the province of gentlemen to being a central force of society; from a financially marginal part of governmental outlays to a significant one; from a minimal part of the academic enterprise to a dominant one. . . .

Science as it is done today, however, really dates back only to the end of World War II, when the U.S. government committed itself to the massive funding of basic scientific investigation.

David Baltimore, Tanner Lectures on Human Values at Cambridge University: On Doing Science in the Modern World, (Mar. 9-10, 1992), *in* The Tanner Lectures on Human Values, 263-65 (Sterling McMurrin ed., Cambridge Univ. Press, vol. 13 1992).

<sup>4</sup> Mildred K. Cho, Glen McGee, & David Magnus, *Research Conduct: Lessons of The Stem Cell Scandal*, 311 Sci. 614, 614-15 (2006).

5

[M]any scientists still cling to an ivory tower mentality founded on precepts such as "science should be done for its own sake," "science is neutral," and "science cannot be blamed for its misapplication." Their logic rests on the distinction between pure and applied science. It is only the application of science that can be harmful, they allege. As for pure science, they say that the scientist's

<sup>&</sup>lt;sup>2</sup> Henry Oldenburg, inspired by Francis Bacon's *Novum Organum*, was the pioneer behind the journal and behind the idea of peer review; Oldenburg would have articles sent to experts for review before including them in the *Philosophical Transactions*. A hundred years later, when the Royal Society took over the editorial process of the journal, the concept of peer review was cemented as a requirement for publication. Subsequently, the notions of wide dissemination and peer review have become general hallmarks of scientific journal publishing. Dov Greenbaum, Joanna Lim, & Mark Gerstein, *An Analysis of the Present System of Scientific Publishing: What's Wrong and Where to Go from Here?*, 28 Interdisc. Sci. Revs. 293, 293 (2003). For a review of seventeenth century scientific advancement, see, e.g., Peter Harrison, *Was There a Scientific Revolution?*, 15 Eur. Rev. 445, 445-54 (2007); Ray Spier, *The History of the Peer-Review Process*, 20 Trends Biotechnology 357, 357 (2002).

These recent debates in research ethics have pitted renowned scientists against each other in determining whether or not science needs to codify a set of ethical rules and regulations.<sup>6</sup> Notwithstanding the reality that basic science researchers are rarely qualified to ever determine or evaluate the eventual ethical issues resulting from downstream application of their research,<sup>7</sup> a particular apprehension of those opposing

only obligation is to make the results of research known to the public. What the public does with them is its business, not that of the scientist.

Sir Joseph Rotblat, A Hippocratic Oath for Scientists, 286 Sci. 1475, 1475 (1999).

<sup>6</sup> See, e.g., Comm. on Sci., Eng'g, and Pub. Policy, Nat'l Acad. of Sci., Nat'l Acad. of Eng'g, & Inst. of Med., On Being a Scientist: Responsible Conduct in Research 20 (2d. ed. 1995) [hereinafter COSEPUP Report] ("Even scientists conducting the most fundamental research need to be aware that their work can ultimately have a great impact on society."); Marie Cassidy, *Introduction: Forum on Responsible Conduct in Biomedical Research*, 224 Proc. Soc'y for Experimental Biology & Med. 203, 204 (2000) ("Compared with 50 or 100 years ago, the pursuit of science as a career has evolved into a cooperative, collaborative undertaking, increasingly interdisciplinary in its execution. Accordingly, there is an urgent need to enunciate and integrate code concepts into the warp and woof of the research cultural fabric."); Sir Joseph Rotblat, Remember Your Humanity, Nobel Prize Acceptance Speech (Dec. 10, 1995) (advocating that scientists should stop assisting in the creation of nuclear weapons).

A common and disturbing feature of the ubiquitous bioethical commentaries is the short shrift—often, complete inattention—given to the feasibility of the technologies under discussion. So many of the commentaries include the caveat "when the technology is good enough" and then carry on with the ethical analyses and risk-benefit assessments. Yet, many of the futurist therapies and fixes are never going to become standard or useful, because the technologies are not now and never will be precise, predictable, and reliably controllable.

Ruth Levy Guyer & Jonathan D. Moreno, *Slouching Toward Policy: Lazy Bioethics and the Perils of Science Fiction*, 4 Am. J. of Bioethics W14 (2004) (advocating scientists ought to limit their imagination); *see also* Irving Lerch, *To Pledge or Not to Pledge: An Oath for Scientists?*, APS News, Mar. 2001, at 8 (warning of the dangers of oaths).

<sup>7</sup> This argument against imposing ethical guidelines is not without merit. *See, e.g.*, Yandell Henderson, *Patents Are Ethical*, 77 Sci. 324, 325 (1933) ("Any new practice rule or regulation that . . . in any way impairs scholarly freedom, will tend rather to diminish than to insure the maintenance of scholarly ethics and faculty morale. Regulations impair ethics."). Similar arguments have been made to support the current expansive scope of patentability within the US patent system. *See generally* Philip Grubb, Patents for Chemicals, Pharmaceutical & Biotechnology (4th ed. 2004). In contrast to the European patent system, the United States patent regime creates a sharp distinction between patenting technology, and the corresponding ethical and moral questions associated with that technology—the so-called "patent first, ask questions later" concept. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 Wm. & Mary L. Rev. 469, 469-70 (2003); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999) (differentiating between morality and utility). *But see* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 Md. L. Rev. 1051, 1075 (1987-88) (stating that new technologies

such an institution is the concern that the opportunity costs will be much greater than the perceived benefits.<sup>8</sup>

Part of what has driven the debate on ethics and morals in science has been a perceived decline in the public's perception of scientists and their research,<sup>9</sup> and a concomitant decline in support for increased science funding.<sup>10</sup> Those in favor of a "do

should be patentable, but that the patent office should reserve "the right to regulate specific applications. This is the only sensible course."). Scholars in favor of this US Patent and Trademark Office (PTO) position argue that the lost opportunities associated with complex ethical bottlenecks at the beginning of the innovation pipeline are too great to support broad limitations. *See, e.g.*, Shirley Tilghman & David Baltimore, *Therapeutic Cloning is Good for America*, Wall St. J., Feb. 26, 2003, at A16 (invoking the calling for of bans on recombinant DNA technology in the late seventies, Baltimore and Tilghman argue, "A broad ban [on therapeutic cloning] would stifle innovation in a key area of biomedical research. . . . We need safeguards, not a ban"). Ethical issues are better dealt with by either trained professionals, or elected officials, not by underpaid and overworked examiners at the patent office. *See, e.g.*, James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 Wm. Mitchell L. Rev. 155, 178 (1994) ("The proper venue for consideration of moral issues of biotechnology is within the regulatory agency entrusted with the product's oversight, not the PTO.").

<sup>8</sup> Throughout this Article I would like to distinguish between clinical research that may require more ethical and moral oversight, and basic science research that may be multiple steps away from even a potential practical technology. This Article deals mainly in issues surrounding basic science research.

<sup>9</sup> See, e.g., Sven Widmalm & Jörgen Nissen, Final Report of the Project: Science and Technology Studies at Uppsala 6 (2004). ("[P]aradox of contemporary science and technology: faith in science and technology as engines of progress has perhaps never been stronger, but at the same time public trust in scientific and technological expertise seems unstable.").

<sup>10</sup> See, e.g., Select Committee on Science and Technology, Science and Society: Third Report, 1999-2000, H.L. 38, §2.41, *available at* 

http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3801.htm. There is no consensus as to what the public actually thinks of science and scientists as there are numerous conflicting reports, studies, surveys, and polls. For an overview of the issues, see, e.g., Wellcome Trust, *Going Public: Public Attitudes to Science and Research*, Dec. 1, 2002,

http://www.wellcome.ac.uk/News/2002/Features/WTD004707.htm. *See also* Baltimore, *supra* note 3, at 298 ("Science is suffering from something of an image problem and for an enterprise so dependent on public support that could mean trouble ahead."). For a study finding generally positive attitudes toward science, see, e.g., Nat'l Sci. Bd., Nat'l Sci. Found., *Science and Technology: Public Attitudes and Public Understanding, in* Science and Engineering Indicators 2002 (2002), *available at* http://www.nsf.gov/statistics/seind02/pdf/c07.pdf . See also the results of the Harris poll: "Only two occupations are perceived to have "very great" prestige by more than half of all adults, scientists (52%) and doctors (52%)." Harris Interactive, *The Harris Poll #65, Doctors, Scientists, Firemen, Teachers and Military Officers Top List as "Most Prestigious Occupations,*" Sept. 15, 2004, *available at* 

http://www.harrisinteractive.com/harris\_poll/index.asp?PID=494; Note also a rise in stature for scientists the following year: "Four occupations are perceived to have "very great" prestige by at least half of all adults - firemen (56%), scientists (56%), doctors (54%), and nurses (50%)."

no harm" provision imposed on all scientists argue that it will help revive faith in basic science research and the scientists who conduct it. If we remove the fear that taxpayer money is going towards a perceived "Franken-science," then the public will be more willing to continue to fund basic science research without overburdening regulation.<sup>11</sup>

This article argues that there are potentially deeper and more important ethical issues in science that first need to be dealt with: the growing threat of fraud and misconduct in research.<sup>12</sup> Faith in science must first come from the unwavering belief by the public that scientists can be trusted to do their job,<sup>13</sup> whatever it entails, and whatever it produces, particularly when it is often being done with taxpayer money.<sup>14</sup> Referring to

Harris Interactive, *The Harris Poll #69, Firemen, Doctors Scientists, Nurses and Teachers Top List as "Most Prestigious Occupations,"* Sept. 8, 2005, *available at* http://www.harrisinteractive.com/harris\_poll/index.asp?PID=599.

Much of the confusion as to where science stands in the public's eye may be attributable to the conflation of science and technology. Whereas somewhere around 80% of the public supports basic science research, technology is viewed with 'suspicion and hostility.' *See, e.g.*, D. Allan Bromley, Sheffield Lecture at Yale University: Science, Technology, and Politics (Mar. 22, 2001) ("Science studies what is; technology creates what never was." (quoting von Karmen)).

<sup>11</sup> Note also that regulation imposed by society from outside of the scientific community may not be able to properly promote scientific ideals as well as change from within. "An ethical climate must be fostered from within the scientific community." Mark Frankel, *Scientific Societies as Sentinels of Responsible Research Conduct*, 224 Proc. Soc'y for Experimental Biology & Med. 216, 216 (2000).

<sup>12</sup> "There's a lot to worry about." Donald Kennedy, *Research Fraud and Public Policy*, 300 Sci. 393, 393 (2003) (noting that hard sciences are not the only sciences that suffer from fraud, in fact, often social scientists have political incentives to commit fraud, something that exists to a lesser degree in basic science research); see also European Sci. Found., Science Policy Briefing 10: Good Scientific Practice in Research and Scholarship 1 (Dec. 2000), available at http://www.esf.org/sciencepolicy/170/ESPB10.pdf ("At a time when the need to build trust between science and society is becoming ever more important, it is vital that the conduct of science itself is based on the highest ethical considerations and that misconduct within science itself can be identified and dealt with in an open and transparent manner."); Pieter J. Drenth, *Responsible Conduct in Research*, 12 Sci. Eng. Ethics 13, 13 (2006) ("Society, politics and the media pose critical questions tending to censorship or at least control of science."); Benjamin Sovacool, Using Criminalization and Due Process to Reduce Scientific Misconduct, 5 Am. J. of Bioethics W1 (2005).

<sup>13</sup> See R. Stephen Berry, *Validity and Ethics in Science*, 300 Sci. 1341, 1341 (2003) (noting it is important for the public to acknowledge and understand that a lack of confidence in scientists because of fraud in science is independent of the confidence that the public should feel towards the scientific process as a whole; science's validation methodologies serve to protect science from the long term effects of bad data).

<sup>14</sup> "Indeed, failure to police a profession vigorously can lead to the general decline in reputation and public acceptance of that profession, which can also result, in the case of a governmentally funded profession, in a decline in monetary support." Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. Mich. J.L. Reform 357, 399

a recent South Korean stem cell scandal, some commentators noted that "scientists fear that the episode will damage not only the public perceptions of stem-cell research, but science's image as a whole."<sup>15</sup> "[E]ven a small number of instances of scientific misconduct is unacceptable and could threaten the continued public confidence in the integrity of the scientific process and in the stewardship of federal funds."<sup>16</sup>

If science is to regain and then maintain its position of trust within society, it has to show that it is itself trustworthy, and that it can police itself properly: <sup>17</sup> "Unless the trust that scientists traditionally extend to each other also characterizes the relationship between science and the public, the research enterprise is likely to become much more encumbered by counterproductive regulation and oversight." <sup>18</sup> Only once science deals with these more pressing issues can the scientific community begin to debate the ethical and moral concerns regarding significant downstream applications of research. <sup>19</sup>

Not that the scientific community has not made some efforts to show an interest, albeit limited, in dealing with the issue of fraud – every couple of years the issue of fraud and misconduct is momentarily revived, and then just as quickly there is a lull again in commentary on research ethics. The scientific community's current inability to deal effectively with fraud, despite this periodic publication routine, implies that the issue is not something that can be solved through infrequent and isolated discussions. Rather, as

<sup>15</sup> Erika Check & David Cyranoski, *Korean Scandal Will Have Global Fallout*, 438 Nature 1056, 1056-57 (2005).

<sup>16</sup> Nat'l Inst. of Health, U.S. Dep't of Health and Hum. Servs., Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 18 NIH Guide For Grants and Contracts 30 at 1 (Sept. 1, 1989), *available at* http://grants.nih.gov/grants/guide/historical/1989\_09\_01\_Vol\_18\_No\_30.pdf.

<sup>17</sup> See Frankel, *supra* note 11, at 216 (noting that recent scandals have at least fueled skepticism among the public as to science's ability, and importantly, willingness, to police itself).

<sup>18</sup> Bruce Alberts & Kenneth Shine, *Scientists and the Integrity of Research*, 266 Sci.1660, 1660 (1994); *see also* Baltimore, *supra* note 3, at 273 ("The regulation of recombinant DNA technology was a model of responsible, effective regulation largely because it was left in the hands of the scientific community."); Daniel J. Kevles, *Preface* to Vannevar Bush, Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research (Nat'1 Sci. Found. 1990) (1945) ("Science still operates best in an environment of freedom, including freedom from security restrictions"); Marcel C. LaFollette, *The Politics of Research Misconduct: Congressional Oversight, Universities, and Science*, 65 J. of Higher Educ. 261, 261 (1994) ("The foundation of public support for science . . . is trust . . . that scientists and research institutions are engaged in the dispassionate search for truth." (quoting Representative John Dingell)).

<sup>19</sup> See, e.g., Glenn Harlan Reynolds, *Thank God for the Lawyers: Some Thoughts on the* (*Mis*)Regulation of Scientific Misconduct, 66 Tenn. L. Rev. 801, 816-18 (1999).

<sup>(1992). &</sup>quot;[T]he more corrosive force is the undermining of public confidence in an important public institution and the engendering of a cynical perception that the reporting and the funding of scientific research is a rigged game." *Id.* at 421.

incentives to commit fraud grow,<sup>20</sup> scientists need to be constantly vigilant. This need will become further magnified as science becomes more intertwined with other aspects of society and policy, resulting in a greater need for science to become outwardly accountable to the public.<sup>21</sup>

This article explores numerous issues relating to fraud in academic basic science research. The next section discusses basic issues of fraud and misconduct in science. It attempts to define fraud and to ascertain its prevalence within the research community. Of particular focus will be determining whether, in dealing with fraudulent activity, the scientific community ought to discriminate in its response to any particular instance of fraud based on the nature and effect of that fraud. The section concludes with a discussion on whether fraud and misconduct in science ought to be a real concern for all scientists.

The following section looks to policy issues in dealing with fraud. This section is divided into three parts looking at who has been and who should be responsible for setting the standards of fraud, teaching about fraud and misconduct to scientists, and policing researchers and enforcing misconduct regulations. Finally, in the conclusion, the article offers a summarized policy recommendation for dealing with fraud and misconduct in science.

The article is particularly apropos given recent events, such as the stem cell scandal in South Korea, which both expose the fact that major fraud continues in science and highlight science's enduring ability to police itself and, eventually, ferret out the truth.

The intense competition for recognition by peers and by the general public, for prizes, for commercial gain, is slowly eroding the scientific ethic, this is the ethic that depends on cooperation among scientists, on a morality that drives out selfishness, one's acknowledgments of and by others. And if this ethos is disappearing, then the citation indices no longer reflect worth but a lack of the scientific communities. The future of the scientific endeavor depends on regaining the scientific soul.

Adil E. Shamoo & Cheryl D. Dunigan, *Ethics in Research*, Experimental Biology & Med. 205, 208 (2000) (quoting Phillip Siekivitz).

<sup>21</sup> See, e.g., Baltimore, supra note 3, at 301.

<sup>&</sup>lt;sup>20</sup> These sorts of incentives might include increased pressure to publish to get a limited number of tenured positions. *See, e.g.*, Martina Franzen, Simone Rodder, & Peter Weingart, *Fraud: Causes and Culprits as Perceived by Science and the Media*, 8 EMBO Reports 3, 4 (2007). According to some,

#### II. FRAUD IN SCIENCE

Fraud has always existed in some form throughout the history of science. Many important and relevant scientists, including Ptolemy,<sup>22</sup> Copernicus, Galileo,<sup>23</sup> Newton,<sup>24</sup> Dalton, Kepler,<sup>25</sup> Mendel,<sup>26</sup> Freud, and Pasteur,<sup>27</sup> have been accused of, and arguably may have actually committed, some fraudulent research over the course of their scientific careers.<sup>28</sup> Fraud has only recently been extensively and openly discussed in scientific circles. Notwithstanding the lack of concern amongst the general rank and file scientists, fraud in science seems to be becoming more prevalent. This apparent surge of fraud may be due to global changes within the scientific community; particularly growing competition for scarce research positions, limited government funding, and a desire for greater recognition for one's scientific achievements.<sup>29</sup>

In the 1980s and early 1990s, the social climate "became decidedly more moralistic,"<sup>30</sup> with politicians eagerly investigating an abundance of allegations, and the media publicizing those (often unfounded) allegations.<sup>31</sup> Concomitant with these

<sup>24</sup> See, e.g., Kreutzberg, supra note 22, at 330.

<sup>25</sup> William J. Broad, *After 400 Years, a Challenge to Kepler: He Fabricated His Data, Scholar Says*, N.Y. Times, Jan. 23, 1990, at C1.

<sup>26</sup> See, e.g., David Goodstein, What Do We Mean When We Use the Term `Science Fraud'?, Scientist, Mar. 2, 1992, at 11.

<sup>27</sup> See generally William Broad & Nicholas Wade, Betrayers of the Truth (1983); Horace Freeland Judson, The Great Betrayal: Fraud in Science (2004); Research Fraud in the Behavioral and Biomedical Sciences (David J. Miller & Michel Hersen eds., 1992).

<sup>28</sup> This underscores Dr. Berry's point that there is a distinction between fraud in science and the validity of science; given that science relies on trial and error as a major component of the scientific process, fraudulent data will rarely become a long-term part of the scientific canon. Berry, *supra* note 13, at 1341.

<sup>29</sup> See, e.g., Franzen, Rodder, & Weingart, *supra* note 20, at 3; *see also* Kreutzberg, *supra* note 22, at 331 (noting that an overlooked reason for the growth in fraud is that fraud tends to beget more fraud; once you have gotten away from it, you do it again, each time more audaciously).

<sup>30</sup> Marcel C. LaFollette, *The Evolution of the "Scientific Misconduct" Issue: An Historical Overview*, 224 Proc. of the Soc. for Experimental Biology & Med. 211, 211 (2000).

<sup>31</sup> *Id.* Noting further that

<sup>&</sup>lt;sup>22</sup> See Georg W. Kreutzberg, *The Rules of Good Science: Preventing Scientific Misconduct is the Responsibility of All Scientists*, 5 EMBO Reports 330, 330 (2004).

<sup>&</sup>lt;sup>23</sup> Keith A. Pickering, The Ancient Star Catalog: A Question of Authorship, Presentation to the 4th Biennial History of Astronomy Workshop at Notre Dame University (July 3, 1999) (transcript available at http://www.nd.edu/~histast4/exhibits/papers/Pickering/index.htm); *see also* Kreutzberg, *supra* note 22, at 330.

institutional witch hunts, there was a growing public frustration with what seemed to be rampant fraud and abuse in government contracting.<sup>32</sup> The public face of science fraud has gone through some evolution in the media over this period. In the 1970s, the language used to describe science fraud emphasized the criminal aspects of fraud in science. Later, in the 1980s, the media's terminology associated with fraud began to soften,<sup>33</sup> and the term misconduct – i.e., "research misconduct," "scientific misconduct," or "misconduct in science" – came into vogue.<sup>34</sup> In parallel, post WWII, discussions of solutions for the issue of fraud and misconduct in science centered on the term "research ethics." In the 1980s there was a definitive shift from an ethics based terminology to the use of language centered on integrity.<sup>35</sup> Recent publications, though, may reflect the beginnings of a much harder stance on fraud, incorporating the much stronger term "corruption."<sup>36</sup>

[T]he increased media attention also happened to coincide with attention to ethical conflicts in all walks of life, from the tribulations of television evangelists and star athletes to the foibles of legislators. Journalistic attention to scientific misconduct helped to spotlight science as yet another area of concern, and it drew politicians like moths to a flame.

#### Id.

<sup>32</sup> *Id*.

<sup>33</sup> See Inst. for the Study of Applied & Prof'l Ethics at Dartmouth College, Research Ethics: A Reader 5 (Deni Elliott & Judy E. Stern eds., 1997). According to the Reader, in law "fraud" is a legal term of art and it:

[R]equire[s] evidence not only of intentional deception but also of injury or damage to victims. Proof of fraud in common law requires documentation of damage incurred by victims who relied on fabricated or falsified research results. Because this evidentiary standard seemed poorly suited to the methods of scientific research, "misconduct in science" has become the common term of reference in both institutional and regulatory policy definitions.).

#### Id. at 216.

<sup>34</sup> Drenth, *supra* note 12.

<sup>35</sup> *Id*.

<sup>36</sup> J Marvin Herndon, *Basic Cause of Current Corruption in American Science, in* Against the Tide: A Critical Review by Scientists of How Physics and Astronomy Get Done 57, 57 (Mart ń López Corredoira & Carlos Castro Perelman eds., 2008), *available at* http://philsci-archive.pitt.edu/archive/00004046/01/againsttide.pdf; Jack T. Trevors & Milton H. Saier Jr, *Corruption and Fraud in Science*, 189 Water, Air & Soil Pollution 1, 1 (2006).

Prior minimal interest in fraud among scientists might have stemmed from the conventional wisdom that fraud in science is rare,<sup>37</sup> that it is usually the act of an unbalanced researcher,<sup>38</sup> that science is a supposedly self-correcting discipline,<sup>39</sup> and that fraud in science is an internal, correctable matter of no relevance or interest to the public. These excuses, however, have lost much of their grounding and validity. And particularly, while paying a growing share of the cost of research, the public has become more interested in the specifics of government funded research and may be losing its patience with the scientific establishment's desire to continue to police itself.

The scientific community may have only recently come to the realization that scientific misconduct, as well as questionable research practices, is endemic and that there are serious costs associated with scientific misconduct, including disruption of research, wasted money and effort spent dealing with fraud, and, importantly, a growing public distrust of science and a defacement of the public image of science.<sup>40</sup>

<sup>39</sup> While controversial, it is often postulated that peer review and the replication of experiments will discover errors and fraud in science. *See* Baltimore, *supra* note 3, at 301. *But see* Brian Vastag, *Cancer Fraud Case Stuns Research Community, Prompts Reflection on Peer Review Process*, 98 J. Nat'l Cancer Inst. 374, 375-76 (2006). According to Vastag, no practical system could reliably detect well-concealed fraud by

[A] scientist intent on covering his or her tracks.

Peer review's strength, . . . is determining whether reported data support an author's assertions . . . "evaluating the study design, to gauge whether it supports the interpretation being made. What it can't get at is determining whether the primary and raw data are true. There are so many steps in processing the raw data, and there are many ways an investigator or data manager could change the data."

Vastag, *supra* at 375-76 (quoting Barnett S. Kramer, editor in chief of the *Journal of the National Cancer Institute*).

<sup>40</sup>Alison Abbott, *Science Comes to Terms with the Lessons of Fraud*, 398 Nature 13, 13 (1999); *see also Japanese Scandals Raise Public Distrust*, 398 Nature 14, 14 (1999) (noting that a recent white paper regarding public perceptions of Japanese science found that scientists were perceived as "insular and unwilling to disclose or share details of their research due to preoccupation with successful results." Thus, despite the "apparently low incidence of scientific misconduct in Japan," the Japanese are somewhat distrustful of their scientists.).

<sup>&</sup>lt;sup>37</sup> See, e.g., Kreutzberg, *supra* note 22, at 330 ("When scientists hear about scientific fraud, they quickly denounce the culprits as not being 'true' scientists. The true scientist, they argue, is

only interested in unveiling step by step the countless enigmas of nature. He or she labours [sic] long hours and weekends at a desk or in the laboratory to find the truth, not to invent it.").

<sup>&</sup>lt;sup>38</sup> See, e.g., K.J. Breen, *Misconduct In Medical Research: Whose Responsibility?*, 33 Internal Med. J. 186, 189 (2003) (noting that research misconduct has been linked to laziness, messianic complex, mental illness and the lack of moral capacity to distinguish right from wrong).

#### A. Fraud/Misconduct Defined

Legally, fraud is defined as "all kinds of acts which have as their objective the gain of an advantage to another's detriment, by deceitful or unfair means."<sup>41</sup> Fraudulent science can be more broadly and simplistically defined as any form of research misconduct with the primary intent to deceive the reviewer and the reader. This broader definition reflects the principal problem created by fraudulent conduct: a breakdown of the trust that underlies the entire profession. Without trust in their peers, scientists cannot feasibly incorporate the multitude of research results that are presented daily in the literature. And, given that science is implicitly built upon the (most probably non-replicated) results of earlier scientists,<sup>42</sup> a breakdown of trust would lead to a breakdown of the entire scientific endeavor as we know it. Thus, fraud becomes all the more relevant in fields where reproducibility is difficult or unlikely, particularly in the biomedical sciences.

Generally, science can be divided into a four-stage research process: production, reporting, dissemination, and evaluation.<sup>43</sup> There are a number of scientific social norms that are important for the production of reliable and certified knowledge. These norms include "honesty, objectivity, tolerance, doubt of certitude, and unselfish engagement."<sup>44</sup> Each of these norms has the potential to break down at any of the four basic stages of research, resulting in some level of fraudulent science.<sup>45</sup>

Some have suggested that it is the breakdown of the unselfish engagement factor in particular that has led to the creation of a fertile environment for fraud. With the increased potential for pecuniary gains or professional fame, scientists may be more tempted than ever to commit fraud.<sup>46</sup> Those who subscribe to this theory could summarize most instances of scientific fraud simply as occasions where scientists

<sup>43</sup> See Daryl E. Chubin, Misconduct in Research: An Issue of Science Policy and Practice, 23 Minerva 175, 179 (1985).

<sup>44</sup> Andre Cournand, *The Code of the Scientist and its Relationship to Ethics*, 198 Sci. 699, 700 (1977).

<sup>45</sup> Chubin, *supra* note 43, at 176-77, outlines seven possible explanations for fraud in science: i) psychopathy, ii) ambition, iii) the publish or perish syndrome, iv) competition for grants, v) the autocratic system of the lab, vi) the limitations of peer review, and/or vii) sloppy work. With regard to sloppy work, see, e.g., Ward Pigman & Emmett Carmichael, *An Ethical Code for Scientists*, 111 Sci. 643, 647 (1950) (noting that "[f]requently [violations of ethical guidelines] are the results of carelessness").

<sup>46</sup> Pigman & Carmichael, *supra* note 45, at 701.

<sup>&</sup>lt;sup>41</sup> The Law Dictionary (Anderson Publ'g Co. 2002).

<sup>&</sup>lt;sup>42</sup> Letter from Sir Isaac Newton to Robert Hooke (Feb. 5, 1675/76) ("If I have seen further it is by standing upon the shoulders of giants.").

allowed selfish considerations to override scientific norms.<sup>47</sup> Others acknowledge that many scientists are "ambitious, self-serving, opportunistic, selfish, competitive, contentious, aggressive, and arrogant," but claim they are nevertheless not crooks.<sup>48</sup> Thus, "it is essential," they claim, "to distinguish between research fraud on the one hand and irritating or careless behavioral patterns of scientists, no matter how objectionable, on the other. We must distinguish between the crooks and the jerks."<sup>49</sup>

There are other, more specific, definitions of fraud: the Office of Science and Technology Policy, the National Science Foundation, and the Office of Research Integrity (ORI), among other agencies,<sup>50</sup> have defined misconduct or fraud narrowly as "fabrication, falsification, plagiarism, or other practices . . . for proposing, conducting, or reporting research."<sup>51</sup> In 1995, ORI's Ryan Commission proposed but failed to get the adoption of "a new federal definition of research misconduct and other professional misconduct related to research. The proposed definition specifies offenses that by themselves constitute research misconduct: misappropriation, interference, and misrepresentation (MIM)."<sup>52</sup> However, at present, even ORI retains the narrow fabrication, falsification, and plagiarism (FFP) designation.<sup>53</sup> The Department of Health and Human Services (HHS) recently published its policies regarding research misconduct. <sup>54</sup> A major change includes the broadening of the definition of misconduct to include fraudulent activity during the peer review process. The rules also give HHS the discretion to respond to allegations of research misconduct when it feels the institutions have not done enough. The rules also replace the ad hoc appeals process, which included

<sup>48</sup> Howard K. Schachman, What is Misconduct in Science?, 261 Sci. 148, 148 (1993).

<sup>49</sup> *Id*.

<sup>50</sup> For example, NASA, the Department of Health and Human Services, the Department of Energy, and the Department of Veteran's Affairs.

<sup>51</sup> Public Health Service Standards for the Protection of Research Misconduct Whistleblowers, 65 Fed. Reg. 70,830, 70,841 (proposed Nov. 28, 2000) (to be codified at 42 C.F.R. pt. 94).

<sup>52</sup> Comm'n on Research Integrity, U.S. Dep't of Health & Hum. Servs., Integrity and Misconduct in Research x (1995), *available at* http://ori.dhhs.gov/documents/report\_commission.pdf.

<sup>53</sup>See, e.g., Office of Res. Integrity, U.S. Dep't of Health & Hum. Servs., Annual Report 2006 2 (2007), *available at* http://ori.dhhs.gov/documents/annual\_reports/ori\_annual\_report\_2006.pdf [hereinafter ORI Annual Report].

<sup>54</sup> Public Health Service Policies on Research Misconduct, 42 C.F.R. §93 (2008) (these regulations substantially revised the former regulations that governed institutions that received PHS money).

<sup>&</sup>lt;sup>47</sup> See, e.g., Breeding Cheats, 445 Nature 242, 242 (2007); see also Peter Doshi, Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?, IEEE Tech. & Soc'y Mag., Spring 2006, at 10 (book review).

a hearing in front of a three-person panel, with a more formal process that includes a hearing before an administrative law judge.<sup>55</sup>

While these and other government agencies have refined their definitions of each of the terms fabrication, falsification and plagiarism, or dropped the often used but vague "other practices clause," a recent report in *Nature* suggests that research scientists perceive the definition of fraud to encompass much more than fabrication, falsification, or plagiarism; listing at least sixteen other forms of fraud with varying degrees of prevalence.<sup>56</sup>

Thus, notwithstanding the efforts to standardize and simplify the definition of scientific misconduct, there remain very fuzzy lines dividing outright falsification and data massaging or human error and outright misconduct; in addition to the other ambiguous forms of science misconduct, ranging from questionable research practices,<sup>57</sup>

<sup>56</sup> Brian C. Martinson, Melissa S. Anderson, & Raymond de Vries, Scientists behaving badly 435 Nature 737, 737 (2005) (referring to these particular types of misconduct as misbehaviors); see also Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28,369, 28,377 (May 17, 2005) ("Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.") (emphasis added). Compare Charles Walter & Edward P. Richards, Defining Scientific Misconduct for the Benefit of Science, Med. & Public Health Law Site, http://biotech.law.lsu.edu/ieee/ieee23.htm (last visited Jan. 28, 2009) (noting the National Academy of Science suggested limiting it to just FFP: Fraud Fabrication and Plagiarism), with ScienceScope: NSF Stakes a Position on Misconduct, 276 Sci. 1779, 1779 (1997) (citing the National Science Foundation's ethics enforcer, Inspector-General Linda Sundro, that the "serious deviation" clause in the definition of misconduct: "fabrication, falsification, plagiarism (FFP), or other serious deviation from accepted practices," is the core of the definition). The NSF is alone in this regard and many other science groups wanted it removed. In fact, given that many scientists found it too vague it was suggested that the White House interagency Committee on Fundamental Science remove it. ScienceScope: NSF Stakes a Position on Misconduct, supra at 1779; see also COSEPUP Report, supra note 6, at 18 (noting that such terminology may impede science as "novel or unorthodox research methods" may fall under the rubric of such language, even though novel or unorthodox methods are sometimes necessary for science to advance).

<sup>57</sup> See, e.g., Charles Walter & Edward P. Richards, *Research Misconduct: Catching the Desperados and Restraining the Zealots*, 13 IEEE Eng'g in Med. & Biology Mag. 142, 144 (1994) (COSEPUP, the National Academies Committee on Science, Engineering, and Public Policy, defines questionable research practices to include "dishonest and/or sloppy research practices such as sharing authorship of articles with noncontributing colleagues, accepting honorary authorship of articles, using facilities for private gain or keeping poor research records." COSEPUP included a further category of misconduct: "other misconduct, which includes sexual harassment, rape, embezzlement, murder, extortion, arson, theft, and violations of government regulations."); *see also* COSEPUP Report, *supra* note 6, at 17 (noting that other actions may also include misconduct, including: "cover-ups of misconduct in science, reprisals against

<sup>&</sup>lt;sup>55</sup> *Id.* This may be a significant worry for researchers as non-scientists may view actions taken by researchers in a worse light than actual scientists, although the new process may result in greater equity and uniformity.

conflicts of interest,<sup>58</sup> mingling grant funds, or general sloppy publication practices. Unfortunately for risk-averse researchers, taking excessive precautions to ensure that they never step over the line can create bottlenecks in scientific research.

### B. Has the Prevalence of Fraud in Science Risen to a Problematic Level?<sup>59</sup>

The simple answer is maybe, but there is little in the way of hard empirical data one way or the other. Actual data showing current levels of fraudulent activity is difficult to collect:<sup>60</sup> Ad hoc calculations of the frequency of serious instances of fraud (i.e., FFP as distinct from the types of fraud presented in Martinson et al.<sup>61</sup>) range widely from a relatively benign 0.001% to a more problematic 1% of all publications.<sup>62</sup>

The data that is available is also inconclusive: recent figures from around the world suggest either a very low incidence of scientific fraud or a dismal reporting record. In the United States, the Office of Research Integrity received 267 allegations of research misconduct in 2006.<sup>63</sup> But research misconduct was found in only fifteen of the thirty five cases that it actually closed that year.<sup>64</sup> "Most Federal agencies win most of their cases before hearing offices in their own agencies. In most cases, the batting average is

whistleblowers, malicious allegations of misconduct in science, and violations of due process in handling complaints of misconduct in science").

<sup>58</sup> Pieter J. Drenth, The Responsible Conduct of Basic and Clinical Research, Presentation at the Warsaw Conference (June 3-4, 2005) (stating that recent studies in JAMA and BMJ have shown a strong correlation between positive outcomes and industry sponsorship).

<sup>59</sup> How much fraud is there? "The correct answer . . . is that nobody knows for sure how much fraud there really is. But, they agreed, somebody needs to find out." Jeffrey Brainard, *As U.S. Releases New Rules on Scientific Fraud, Scholars Debate How Much and Why It Occurs*, Chron. Higher Educ., Dec. 8, 2000, at A26, *available at* http://chronicle.com/weekly/v47/i15/15a02601.htm.

<sup>60</sup> See, e.g., Eliot Marshall, *How Prevalent Is Fraud? That's a Million-Dollar Question*, 290 Sci. 5497, 5498 (2000). *But cf.* Murat Cokol et al., *How Many Scientific Papers Should be Retracted?*, 8 EMBO Rep. 422, 423 (2007), *available at* http://www.nature.com/embor/journal/v8/n5/pdf/7400970.pdf. *See also* Ana Marušić, *Author Misconduct: Editors as Educators of Research Integrity*, 39 Med. Educ. 7, 7 (2005); Martin F. Shapiro & Robert P. Charrow, *The Role of Data Audits in Detecting Scientific Misconduct. Results of the FDA Program*, 261 JAMA 2505, 2505 (1989).

<sup>61</sup> Martinson, Anderson, & de Vries, *supra* note 56, at 737.

<sup>62</sup>See, e.g., Nicholas H. Steneck, Protecting the Integrity of Science—Scientific Misconduct, Address at AAAS Forum on Science & Technology in Washington D.C. (Apr. 20-21, 2006).

<sup>63</sup> ORI Annual Report, *supra* note 53, at 3.

<sup>64</sup> *Id.* at 1.

over 70 or 80 percent."<sup>65</sup> The inability to make the charges stick even in internal hearings may indicate an even smaller number of instances of true fraud than the number of claimed fraudulent activities suggests; or it may be that these cases are very hard to win. Of the eight cases where fraud was found in 2005, one involved plagiarism.<sup>66</sup> In the United Kingdom only thirteen cases of scientific fraud have been brought before the Committee on Publication Ethics in the years spanning 1998 to 2003.<sup>67</sup> In 2004, of forty-five cases reported to the German Research Foundation, misconduct was found in only one instance.<sup>68</sup>

One possible take-home message is that detecting provable fraud is difficult. Without outright acknowledgement by the perpetrators, even finding fraud in individual publications is difficult. To find and document most instances of fraud, a peer reviewer would have to closely monitor all ongoing experiments, particularly if a scientist is meticulous in her attempts to deceive the reviewer.<sup>69</sup> And, even when fraud is alleged, it is challenging, as seen from the Office of Research Integrity's statistics, to accurately prove that fraud or misconduct actually took place.<sup>70</sup>

One potential measure of fraud would be a value related to the number of retractions of printed articles. Still, a recent analysis has shown that of the (dismally low) 395 retractions out of 9 million articles published in Medline between 1982 and 2002, most were retracted due to unintentional mistakes or errors, not instances of outright scientific misconduct.<sup>71</sup> But, interestingly, what is most telling about the retraction data is that the source of most retractions is high impact journals. This would suggest that all of science would require the level of scrutiny afforded to the most well publicized articles to ferret out fraudulent activities. Notwithstanding these problematic figures, fraud remains a serious concern in the sciences. Each individual instance of fraud, particularly when it

<sup>67</sup> Id.

<sup>68</sup> Id.

<sup>70</sup> Laura Bonetta, *The Aftermath of Scientific Fraud*, 124 Cell 873, 875 (2006) (saying of the 2700 allegations of fraud submitted to ORI, there have been to date only 160 findings of actual fraud).

<sup>&</sup>lt;sup>65</sup> Gina Kolata, *Inquiry Lacking Due Process*, N. Y. Times, June 25, 1996, at C3 (quoting Robert Charrow).

<sup>&</sup>lt;sup>66</sup> Lucy Odling-Smee, Jim Giles, Ichiko Fuyuno, David Cyranoski & Emma Marris, *Misconduct Special: Where Are They Now?*, 445 Nature 244, 245 (2007).

<sup>&</sup>lt;sup>69</sup> Editorial, *Beautification and Fraud*, 8 Nature Cell Biology 101, 101 (2006). It is unlikely, though, that any change to peer review could actually beef up our fraud detection abilities. Peer reviewers therefore must be more vigilant in their efforts to find fraudulent data. They have to stay watchful but not distrustful.

<sup>&</sup>lt;sup>71</sup> Sara B. Nath et al., *Retractions in the Research Literature: Misconduct or Mistakes?*, 185 Med. J. Austl. 152, 152-53 (2006).

is well publicized, further erodes the public trust in science and the funding that comes with that trust.  $^{72}$ 

## C. Repercussions of Fraud

1. Loss to the General Public

Of greatest concern is the threat to human health and life when there is fraud in science, particularly in biomedical science and FDA clinical trials.<sup>73</sup> Scientists who commit fraud at this level should be held to higher standards and punished with more rigorous sanctions.<sup>74</sup>

The Federal Budget for 2006 proposed nearly 128 billion dollars for federally supported research and development, comprising nearly 20% of the discretionary budget.<sup>75</sup> Officially, health related research receives almost 29 billion dollars and general science receives 6.5 billion dollars, but the Departments of Defense and Energy are also major recipients of federal funds and grants for basic science research. Whatever the eventual total, the taxpayer is spending a lot on science and therefore has a legitimate right to know that this large chunk of money is being put toward noble and useful causes.<sup>76</sup> When a researcher uses government money to fund his or her fraudulent activities, he or she not only squanders taxpayer dollars, but also imposes an opportunity

<sup>73</sup> But see Marc Buyse et al., *The Role of Biostatistics in the Prevention, Detection and Treatment of Fraud in Clinical Trials*, 18 Stat. Med. 3435, 3436 (1999) ("Many instances of fraud in clinical trials, although morally reprehensible, have a negligible impact on the trial's scientific conclusions.").

<sup>74</sup> See, e.g., Barbara K. Redman & Arthur L. Caplan, *Off with Their Heads: The Need to Criminalize Some Forms of Scientific Misconduct*, 33 J.L. Med. & Ethics 345, 347 (2005). This seems a little hyperbolic. Human lives are rarely if ever at stake when basic science researchers commit fraud. In fact, given the inherent replication component in the process of science, one could argue the opposite, that individual acts of fraud rarely have serious implications because other researchers always question and re-test results.

<sup>&</sup>lt;sup>72</sup> Jordan J. Cohen, A Word from the President: Research Integrity is Job One, Ass'n of Am. Med. Colleges Reporter, Sept. 2005, available at

http://www.aamc.org/newsroom/reporter/sept05/word.htm ("Few things are more damaging to the reputation of academic medicine than published instances of scientific 'misconduct.'"). See also Alison Abbott & Phillip Graf, Survey Reveals Mixed Feelings Over Scientific Misconduct, 424 Nature 117, 117 (2003) ("[I]ncreased reporting of research misconduct in the media . . . is damaging public confidence in science.").

<sup>&</sup>lt;sup>75</sup> See, e.g., Bromley, supra note 10.

<sup>&</sup>lt;sup>76</sup> John D. Dingell, *In Science Fraud Case, Justice is Denied; Valid Concerns*, N.Y. Times, July 2, 1996, at A14 ("We must do better to insure that scientific research maintains the trust of the American people, which underlies the commitment of taxpayer dollars.").

cost on more morally inclined researchers who could have used some (more) of the public's funding.

Additionally, in the competitive patenting environment, particularly in the United States where patent interference actions are an integral part of establishing priority and patents are awarded to the first to invent, unscrupulous scientists have held up peer review processes,<sup>77</sup> or have used information from a publication for their own advantage in close patent races.<sup>78</sup> Patents are an important component of the technology transfer mechanism in many countries, including the United States. Illegitimately holding up the patenting process prevents technologies from reaching the public where they can be commercialized and used to the public's advantage. Many of those inventions are not published until their patent rights are belatedly assured.

Regrettably, it seems that there are often no hard and fast rules to prevent such occurrences in the peer review process. Journals tend to be terse in describing their rules on the confidentiality of peer reviews.<sup>79</sup> Neither journals nor local or national police forces may even have jurisdiction over a peer reviewer, who may not be in the same country as the journal and may not be punishable under local laws.<sup>80</sup> The international nature of science suggests that a uniform and universal system needs to be created to determine what ought to be considered fraud and how it should be punished.

2. Losses to Science

Science relies on prior research to push forward and innovate. Notwithstanding conventional wisdom that may imply otherwise, most experiments are not independently replicated by other labs, limiting the ability of scientists to ever uncover their peers' fraud; repetition may occur within the lab conducting the experiment in question as verification prior to actual publishing, but different labs rarely repeat complicated experiments conducted by their peers.<sup>81</sup>

<sup>79</sup> Journals counter that they rarely see evidence of misuse or misconduct among their peer reviewers. *See, e.g., id.* at 1913 (citing John Maddox, editor of *Nature*).

<sup>80</sup> Troy, *supra* note 77, at 63.

<sup>&</sup>lt;sup>77</sup> For example, tampering with evidence that might show that an inventor was the first to invent. *See, e.g.*, Edwin Flores Troy, *Publish and Perish: Patentability Aspects of Peer Review Misconduct*, 5 Tex. Intell. Prop. L. J. 47, 48 (1996) (noting that even with peer reviewers signing a confidentiality agreement, the simple violation of that contract will destroy an inventor's right to patent).

<sup>&</sup>lt;sup>78</sup> See, e.g., Eliot Marshall, Suit Alleges Misuse of Peer Review, 270 Sci. 1912, 1912 (1995).

<sup>&</sup>lt;sup>81</sup> See, e.g., Baltimore, *supra* note 3, at 285 ("[G]iven the many variables that differentiate one laboratory environment from another, the inability to repeat a result is not particularly surprising. [Additionally] there are too many interesting questions abroad for many scientists to be willing to repeat an observation with any exactitude. Repetition is just not as exciting as finding something new."); *see also* Jim Giles, *The Trouble with Replication*, 442 Nature 344, 344 (2006) ("[M]any

Moreover, the specialization of scientists into sub-specialties and their associated jargon has Balkanized much of the literature to a point where research papers and their arcane language are often only accessible to the small initiated subfield. The complex verbiage shuts out the vast majority of other scientists. Researchers cannot afford to spend limited resources and time following up on a result outside of their specific purview of knowledge, thus leaving unexposed results that are fraudulent or fabricated.

David Baltimore nevertheless argues that while repetition does not occur, there are other forms of verification that can limit the negative effects of scientific misconduct within the scientific literature.<sup>82</sup> "[S]cience will root out ineffective ideas, however they were generated;"<sup>83</sup> and although the "mills of science grind slowly[,] . . . they grind exceedingly small" with the result that irreproducible results will eventually get sidelined.<sup>84</sup>

Even if fraud would not result in long term harm to the body of scientific knowledge, there are other potential negative effects: (i) allegations of cheating in science create a stigma that engulfs the entire scientific community; (ii) charges of fraud delegitimize the profession of science in the eyes of the public; <sup>85</sup> and (iii) when an individual commits or is suspected of committing fraud, the careers of coauthors, colleagues, students, and collaborators all potentially suffer.<sup>86</sup> Even suspected fraud has a negative effect on science.<sup>87</sup>

<sup>82</sup> These include, principally, the incorporation of prior results into the design of a new experiment: if the new experiment doesn't work, the experimenter may not even care to verify the result, but rather, she will just publish a limitation on that result's applicability. As further experiments relying on the original experiment fail, its applicability becomes even more cabined, until the scientific community no longer considers it applicable and consigns it to some sort of literary limbo. Baltimore, *supra* note 3, at 287 ("[L]iterature has millions of such papers in it, ones that made no positive contribution to the ongoing process of accumulation of knowledge.").

83

In summary, the publication of false data is morally wrong, disruptive, and eroding of one of the key currencies of science, trust. But its effects are transient and easily absorbed within the ordinary activities of science and, I dare say, most fabrication is probably not unmasked but has little long-term result because the processes of science handle the problem.

#### Id. at 290.

<sup>84</sup> Cherry Murray & Saswato Das, *The Price of Scientific Freedom*, 2 Nature Materials 204, 205 (2003).

<sup>85</sup> See, e.g., Chubin, supra note 43, at 175.

<sup>86</sup> See, e.g., Bonetta, supra note 70, at 873.

<sup>87</sup> See generally Daniel Kevles, The Baltimore Case: A Trial of Politics, Science, and Character (1998).

papers, especially in minor journals, go unreplicated simply because of lack of interest (a third of all papers are never again cited in the scientific literature).").

Importantly, fraud in science invites outside regulation and oversight. While a more transparent scientific process may help promote faith in scientists and their endeavors, regulations might negatively affect trust within the scientific community, turning every colleague into a potential disgruntled whistleblower.<sup>88</sup>

#### 3. Normal Misbehavior

There may be positive externalities associated with some lesser forms of scientific fraud, particularly in the outer reaches of cutting edge scientific research where it might be necessary to bend the rules. Science, as a self-policing profession, creates often extensive, entangled rules to prevent misconduct and fraud. But in some instances, scientists may be able to break the rules without actually going over the line. It is in these instances where science can and does benefit from misconduct. The aforementioned great scientists accused of fraud are particularly good examples of this practice, sometimes substituting what they knew must be correct for their actual error-tinged experimental results.<sup>89</sup>

For example, while it may be wrong to commingle funds from different grants, funding for controversial or unproven technologies is often hard to come by. And although mixing funds from different sources is a slippery slope and often easy to justify for the cash-strapped and morally confident scientist, a number of important scientific discoveries have probably resulted from misused grant funds.

Additionally, experienced scientists might drop outliers in their data or add in fudge factors,<sup>90</sup> relying not on scientific rigor but on honed hunches, justifying the disposal of those points as spurious. Again, dropping data points without scientific justification may border on falsification of data, or not. The gut reaction, acceptable in

<sup>88</sup> LaFollette, *supra* note 30, at 211.

[T]he initial [limited] reactions of many scientists who purported to speak for all of science, coupled with delays in university investigations and the development of ethics codes, not only resulted in further expansion of the federal regulatory presence on university campuses but also helped to create a situation in which an accusation of misconduct, whether warranted or not, can now trigger years of expensive and time-consuming litigation.

Id.

<sup>89</sup> See supra notes 22, 23, 25, and 26.

<sup>90</sup> Possibly most famously, Albert Einstein added a cosmological constant into his theory of General Relativity. *See, e.g.*, Sten Odenwald, *Einstein's Cosmic Fudge Factor*, 81 Sky & Telescope 362, 362 (1991). Note that although Einstein later retracted this constant, his hunch may be vindicated. Press Release, University of Toronto, Was Einstein's Biggest Blunder a Stellar Success? (Nov. 22, 2005), *available at*,

http://www.cfht.hawaii.edu/News/SNLS\_Nov2005/SNLS\_AAS\_PR.html (reporting findings of the Canada-France-Hawaii Telescope's SuperNova Legacy Survey).

many other areas of life, might be necessary when researching uncharted corners of science.<sup>91</sup>

#### **III. POLICY SUGGESTIONS FOR DEALING WITH FRAUD**

## A. Setting Standards<sup>92</sup>

The lack of established procedures for dealing with academic fraud is a major concern.<sup>93</sup> "There is no more important task in dealing with misconduct and promoting integrity in scientific research than developing standards of research conduct."<sup>94</sup> Still, there is no universal understanding of what exactly can be defined as fraud.<sup>95</sup> And even within the established procedures, there remains no rigorous systematic process for

One gray area that I am fascinated by . . . is culling data based on your 'experience.' . . . [T]here was one real famous episode in our field . . . [where] it was clear that some of the results had just been thrown out. . . . [When] queried [the researchers] . . . said, 'Well we have been doing this for 20 years, we know when we've got a spurious result . . . .' [When that happens] . . . [d]o you go back and double check it or do you just throw it out . . . [and] do you tell everybody you threw it out? I wonder how much of that goes on? (quoting a scientist-interviewee).

#### Id.

<sup>92</sup> Many contend that the actual setting of a standard is not the important part of the process. For example, Pigman and Carmichael note that the actions leading up to the establishment of any creed is a useful exercise, as it will create and foster dialogue. Pigman & Carmichael, *supra* note 45, at 647 ("What matters is that scientific men should argue and discuss the matter of scientific ethics as one of infinite importance to themselves and the rest of mankind with the same honesty, humility and resolute regard for the facts they show in their scientific work." (quoting A.V. Hill)).

<sup>93</sup> Marcia Angell, *Fraud in Science*, 219 Sci. 1417, 1418 (1983).

<sup>94</sup> Frankel, *supra* note 11, at 217 ("[T]he scientific community has a responsibility to its members and to society at large to define as precisely as possible what constitutes accepted practices . . . .").

<sup>95</sup> See generally Geoff Brumfiel, *Misconduct? It's All Academic*, 445 Nature 240, 240 (2007) (noting that academia's approach to scientific misconduct is "riddled with inconsistencies"). In light of the potential civil and criminal penalties, exacting standards need to be set. Still, the standards need to be flexible so that they can be applied to often complex cases. *See, e.g.*, Bratislav Stankovic, Comment, *Pulp Fiction: Reflections on Scientific Misconduct*, 2004 Wis. L. Rev. 975, 1007 (2004). Additionally, if there are to be criminal penalties, a specific level of *mens rea* also needs to be defined. *Id.* at 1006.

<sup>&</sup>lt;sup>91</sup> See, e.g., Raymond de Vries et al., Normal Misbehavior: Scientists Talk about the Ethics of Research, 1 J. Empirical Res. on Hum. Res. Ethics 43, 45 (2006).

dealing with many of the issues raised by science fraud. <sup>96</sup> This is an old and continuing problem: "[t]he absence of norms . . . was [also] symptomatic of the neglect of research ethics in the decades leading to the 1980s."<sup>97</sup>

Current efforts by academic institutions to deal with fraud have proved capricious and incomplete: investigations are often drawn out and time consuming; those involved with the investigatory process typically do not have the proper legal and scientific training; and in the end, most universities are unwilling to admit to a fraudulent event out of fear that it will tarnish their reputation, lead to libel suits, and hurt faculty morale.

Setting consistent and universal standards should be the first priority in dealing with science fraud; it is easier to "weigh behavior against pre-established standards"<sup>98</sup> than to deal with each issue de novo and without any precedent. However, codifying morality is difficult,<sup>99</sup> and given the international nature of present-day science research, setting standards that work across all cultures is a complex problem.<sup>100</sup>

It is important that scientists devise these standards, rather than outside governmental forces.<sup>101</sup> Even the United States government acknowledges academia's concern over incorporating law enforcement and the judiciary into scientific disputes, particularly the adversarial culture that involving the legal system would create.<sup>102</sup> Lawyers and policy makers tend toward broad, amorphous, and unrealistic standards,<sup>103</sup>

<sup>98</sup> Julius S. Youngner, *The Scientific Misconduct Process: A Scientist's View from the Inside*, 279 JAMA 62, 64 (1998).

<sup>99</sup> See Stankovic, supra note 95, at 1005.

<sup>100</sup> Funding agencies, like the NSF, have often been at the forefront of setting such standards. See, e.g., Research Misconduct Definitions, 45 C.F.R. §689.1(a) (2007). But science societies and journals with their international clout and presence may be prime candidates for creating such standards. See, e.g., Pieter J. Drenth, President of All European Academies, Scientific Integrity and Social Responsibility: The Role of Academies of Sciences and Humanities, Address at the 2005 World Science Forum Budapest (Nov. 10-12, 2005).

<sup>101</sup> See generally infra note 107.

<sup>102</sup> Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28,369, 28,370 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93).

103

Science fraud is, at least in some ways, a very real problem. But the political and legal system's efforts to deal with it in the standard way, by setting up an ethics bureaucracy and promulgating formal rules based on appearances has been

<sup>&</sup>lt;sup>96</sup> See, e.g., Gary Taubes, *Misconduct: Views from the Trenches*, 261 Sci. 1108, 1108 (1993); see also Brumfiel, supra note 95, at 240.

<sup>&</sup>lt;sup>97</sup> Online Research Ethics Course,

http://ori.hhs.gov/education/products/montana\_round1/research\_ethics.html (last visited Oct. 28, 2008) (quoting Caroline Whitebeck).

whereas scientists favor definitive and narrow standards that lessen uncertainty, <sup>104</sup> which often has a chilling effect on science.

"[T]here is a notable clash of cultures between the disciplines of law and science, and nowhere is this clash more evident than in the lengthy, but still very current, battle over appropriate definitions, rules and procedures concerning legal controls over scientific misconduct."<sup>105</sup> Scientists have to know, particularly if their actions are to be criminalized, what the government considers to be fraud, so as to not unnecessarily chill scientific advancement. Thus, standards have to be narrowly defined, not open-ended and not legalistic.<sup>106</sup>

#### B. What Should be Considered Fraud or Misconduct

Any definition of fraud should presumably attempt to be unambiguous<sup>107</sup> and narrow. Additionally, whatever the definition of fraud is, it is important that it strives to be universal, as the shoulders that we stand on and rely on could be anywhere in the

an abject failure . . . . '[ORI] was after something abstract and elusive. ORI wanted scientists to be perfect.'

Glenn Harlan Reynolds, "Thank God for the Lawyers": Some Thoughts on the (Mis)Regulation of Scientific Misconduct, 66 Tenn. L. Rev. 801, 814 (1999) (quoting Malcolm Gladwell).

<sup>104</sup> Howard Schachman, *From "Publish or Perish" to "Patent and Prosper"*, 281 J. Biological Chemistry 6889, 6898 (2005).

<sup>105</sup> Jesse A. Goldner, *The Unending Saga of Legal Controls Over Scientific Misconduct: A Clash of Cultures Needing Resolution*, 24 Am. J.L. & Med. 293, 293 (1998).

<sup>106</sup> While the legal profession may be used to dealing with such types of standards, particularly those that are designed to be narrowed and defined over time by case law, this concept is foreign to science. *See, e.g.*, Letter from Ralph A. Bradshaw, President Fed'n of Am. Societies for Experimental Biology, Coalition of Biological Sci., to William F. Raub, Sci. Advisor, Office of Sci. Policy, Dep't of Health & Hum. Servs. (May 13, 1996), *available at* http://opa.faseb.org/pdf/crisraub.pdf.

<sup>107</sup> A difficulty in finding an unambiguous definition is that ambiguity is inherent in scientific research, making it difficult to draw a clear line as to what is acceptable and what is not. *See, e.g.*, Frederick Grinnell, *Truth, Fairness, and the Definition of Scientific Misconduct,* 129 J. Lab. & Clinical Med.189, 189-90 (1997). Grinnell notes that what some may think of as fraudulent, others consider a proper research technique. *Id.* at 190. Grinell, quoting the autobiography of Rita Levi-Montalcini, 1986 Nobel Prize Laureate in Physiology or Medicine, noted that Professor Levi-Montalcini applied what some have termed "the law of disregard of negative information . . . facts that fit into a preconceived hypothesis attract attention, are singled out, and remembered. Facts that are contrary to it are disregarded, treated as exception, and forgotten." *Id.* Grinnell subsequently notes that research papers only present selected data, in an unnatural order, lacking all the false starts and mistakes along the way in the experimental process; is this revisionist history, the scientific paper, a fraud? *Id.* at 191. An ambiguous definition of fraud may encompass such actions.

world. Yet, at the same time, misconduct concerns need to be specific to a given area of science – distinguishing between norms, for example, in clinical and basic science research<sup>108</sup> or in academia and industry.<sup>109</sup>

Conceptually, one could envision a multi-tiered system of different degrees of fraud, with corresponding levels of punishment for each violation.<sup>110</sup> Tiers could be filled differently, depending on the norms of the particular branch of science. Even within a relatively narrow definition of scientific misconduct,<sup>111</sup> it seems unfair to punish all actions equally, especially given the career ending outcomes that can arise from being accused and/or convicted of fraud.<sup>112</sup> Such a tiered system might be similar in its design to typical assault statutes. These tiers could be applied to most general cases of fraud and misconduct, although there may be notable instances where the tiered system would break down.

Outside of universal moral and ethical considerations, science should primarily be concerned with fraudulent scientific activity insofar as it impedes innovation or the progress of science. Thus, in examining fraudulent actions, this article proposes that every analysis begin with two components. The first component of the analysis looks to the person committing the act: what is her motivation and intent? The second component looks to the eventual action: what is the actual or potential outcome of this event, vis-à vis scientific progress? While legal definitions might treat both components of the analysis equally, science should be principally concerned with fraudulent actions that, at a minimum, impact the second component of the analysis. Those that only involve the

<sup>109</sup> See, e.g., Floyd E. Bloom, Editorial, *Unseemly Competition*, 287 Sci. 589, 589 (2000) (noting that FFP is rare and there are other more insidious forms of misconduct that are often justified by the perpetrators).

<sup>110</sup> See Grinnell, supra note 108, who gives three criteria for defining misconduct: i) that the actions are never part of scientific practice, ii) that the single action is sufficient to show misconduct, and iii) that there is a specific intent to deceive, implicit in the action of the offender. These criteria seem, though, to exclude most of the authorship issues that are endemic to science, and that are included in the Vancouver Guidelines. See Int'l Comm. of Med. J. Eds., Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (2008), available at http://www.icmje.org/ [hereinafter Vancouver Guidelines].

<sup>111</sup> See Jocelyn Kaiser, *Policing of Science: A Misconduct Definition that Finally Sticks?*, 286 Sci. 391, 391 (1999) (noting how many are concerned that broad, open-ended definitions of misconduct could chill innovation).

<sup>112</sup> Peter Hofschneider, emeritus director at the Max Planck Institute for Biochemistry, notes that young scientists "should not necessarily have their whole research career destroyed because of one misdemeanor." Abbott and Graf, *supra* note 72. Note also comments from a survey where it was found that many scientists felt that it was "unrealistic to demand strict adherence to good scientific practice in all circumstances." Even an indictment with a subsequent exoneration can hurt a scientist's career. *Id.* at 117.

<sup>&</sup>lt;sup>108</sup> See, e.g., Frederick Grinnell, *Misconduct: Acceptable Practices Differ by Field*, 436 Nature 776, 776 (2005).

first component, but have little to no bearing on the second, ought not to be as great a concern to science.

This relatively simple-minded analysis can be used to distinguish among general categories of fraudulent activity. In addition, the analysis might also be used to find particular instances where an activity, while otherwise not truly fraudulent, might be considered fraudulent given the totality of the circumstances. Thus additional information regarding the pattern of occurrences, the impact on others, the scientist's state of mind, and the actions relative to the community standards are very much relevant to any investigation into scientific misconduct.<sup>113</sup> Intent may also be an important component here, and, when viewed on a case-by-case basis, instances of scientific misconduct should be differentiated based on whether there was malicious intent, recklessness, or negligence.

With this distinction in mind we can subdivide what was once globally lumped together as fraud into distinctive tiers – each tier successively having a lesser negative effect on science.<sup>114</sup>

#### 1. First Tier Fraud

A first-tier fraudulent activity would include activities that have damaging effects on the entire scientific system. These would include cases of misconduct such as the fabrication or falsification of data. Such conduct has the potential to significantly impair scientific research, as research builds upon prior knowledge within the body of science. Thus, if data is fabricated or false, all subsequent downstream research has the potential to suffer. Scientists involved in that research will have to endure wasted time, resources, and lost productivity. And, if the fraud remains undiscovered, there is also the potential for a negative impact on downstream technological or clinical applications.<sup>115</sup> Society

<sup>&</sup>lt;sup>113</sup> Christine C. Boesz, Investigations & International Cooperation, Presentation at the ESF-ORI First World Conference on Research Integrity (Sept. 16-19, 2007).

<sup>&</sup>lt;sup>114</sup> But see Brian Martin, Scientific Fraud and the Power Structure of Science, 10 Prometheus 83, 83 (1992), available at http://www.uow.edu.au/arts/sts/bmartin/pubs/92prom.html (noting that fraud is not "clear-cut").<sup>115</sup> See, e.g., Katherine Unger & Jennifer Couzin, Cleaning Up the Paper Trail, 312 Sci. 38, 41 (2006) (The authors found that there have been instances where fraud has been found in basic science research that have resulted in questioning clinical applications based on that data. Just imagine someone in New Zealand reads this paper and says, "That's cool. I can do this with my Patients.") (citations omitted).

<sup>&</sup>lt;sup>115</sup> See, e.g., Katherine Unger & Jennifer Couzin, *Cleaning Up the Paper Trail*, 312 Sci. 38, 41 (2006) (The authors found that there have been instances where fraud has been found in basic science research that have resulted in questioning clinical applications based on that data. Just imagine someone in New Zealand reads this paper and says, "That's cool. I can do this with my Patients.") (citations omitted).

relies on the accuracy of the scientific record in every step of the scientific discovery process – to knowingly add bad information hurts everyone, potentially severely.<sup>116</sup>

This type of fraud/misconduct also typically implies a specific intent to deceive; given that science relies heavily on trust, such actions hurt science globally as they tend to erode trust and promote cynicism among fellow scientists. One could also imagine that an undisclosed conflict of interest would also be considered first tier fraud as it seriously undermines the veracity of the data created.

#### 2. Second Tier Fraud

A lesser violation of fraud might include plagiarism.<sup>117</sup> While unquestionably an unethical act,<sup>118</sup> the repercussions of the action are less severe,<sup>119</sup> and not as likely to harm the institution of science as a first tier type action.<sup>120</sup>

For example, one form of plagiarism that particularly offends the publishing community is that of self-plagiarizing.<sup>121</sup> Although currently not well-defined, self-plagiarism can range from outright malicious attempts to use previously published material to fraudulently enhance one's curriculum vitae to the less serious reuse of an introduction from an older paper in a more recent publication. Here, although it does bring redundancy to the corpus of scientific literature, and may create an extra burden on editors and reviewers, these types of plagiarism do not damage the authenticity of the research, and as such should not be deemed as egregious as tier one fraudulent activities.

<sup>117</sup> But see Shawn G. Clouthier, *Plagiarism Erodes Scientific Integrity*, 301 Sci. 311, 311 (2005).

<sup>118</sup> See, e.g., Brian Martin, Academic Credit Where It's Due, 7 Campus Rev. 11, 1 (1997) ("Plagiarism is often treated like a mortal sin. It is assumed to happen only rarely and to warrant the most extreme penalties when discovered. Students are warned against perpetrating this heinous crime and then, if discovered, may be given a fail for an essay or sometimes an entire course."); see also COSEPUP Report, supra note 6, at 17 (noting that "forfeited recognition to others, and feelings of personal betrayal-can be devastating").

<sup>119</sup> See Kreutzberg, *supra* note 22, at 331(loosely analogizing scientific misconduct to doping in professional sports because just as other athletes see doping as an unfair advantage, other scientists see plagiarism, or receiving credit for work one didn't do, as an unfair advantage over one's peers).

<sup>120</sup> See, e.g., Random Samples: Kinder, Gentler Plagiarism Policy?, 283 Sci. 483, 483 (1999) (noting that Johns Hopkins University required only that Assistant Professor Anish Bhardwaj give a public apology after it was discovered that he plagiarized 40% of a recent editorial).

<sup>121</sup> Jim Giles, *Taking on the Cheats*, 435 Nature 258, 258 (2005).

<sup>&</sup>lt;sup>116</sup> See Editorial, Complacency about Misconduct, 427 Nature 1, 1 (2004) (noting that most journals do nothing to combat plagiarism); see also Editorial, Clamp Down On Copycats, 438 Nature 2, 2 (2005).

This article is not advocating that plagiarism is a victimless crime<sup>122</sup> – those whose ideas are stolen are obviously harmed to some degree. Instead, this article simply advocates that scientific progress is typically not harmed through plagiarism, and not to the same extent that results from falsification and fabrication.

Richard Posner, a Federal Circuit Judge for the Seventh Circuit, suggests that the communal abhorrence of plagiarism be toned down, narrowing the definition to include instances of outright fraud, which require harm to others as an integral component. Plagiarism, Judge Posner opines, should only include instances where there is harm to competitors, the audience, or the source.<sup>123</sup>

It is not clear to this author why plagiarism is most often associated with the greater offenses of fraud and fabrication. Perhaps this association can be explained by analogizing plagiarism and its lesser, sister offense, the failure to properly acknowledge a source, to the legal evidentiary rule of chain of custody. This evidentiary rule is part of the requirement of authentication or identification of evidence. It is designed to remove any doubt as to the identity and authenticity of a piece of evidence, <sup>124</sup> and is most often

<sup>124</sup> See, e.g., Fed. R. Evid. 901.

Rule 901. Requirement of Authentication or Identification

General provision. The requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims.

Illustrations. By way of illustration only, and not by way of limitation, the following are examples of authentication or identification conforming with the requirements of this rule: (1) Testimony of witness with knowledge. Testimony that a matter is what it is claimed to be.

(4) Distinctive characteristics and the like. Appearance, contents, substance, internal patterns, or other distinctive characteristics, taken in conjunction with circumstances.

*Id.*; *see also* Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 901.03 (Joseph M. McLaughlin ed., Matthew Bender 2008) (1975).

The chain of custody method is not mentioned in Rule 901(b)'s list of illustrative methods of authentication. However, it can be viewed as a hybrid form of listed methods. It involves both the testimony of one or more witnesses with knowledge . . . and the distinctive characteristics of the evidence, taken in conjunction with circumstances (Rule 901(b)(4) . . . .)

Weinstein & Berger, supra at §901.03.

<sup>&</sup>lt;sup>122</sup> See, e.g., Yudhijit Bhattacharjee, *Newsmakers*, 317 Sci. 1841, 1841 (2007), for the comments made by Nicholas Steneck at the first World Conference on Research Integrity.

<sup>&</sup>lt;sup>123</sup> Richard A. Posner, In Defense of Plagiarism, Forbes, Jan. 29, 2007, at 32.

used, although not exclusively, in criminal cases.<sup>125</sup> For example, in proffering evidence of a defendant's possession of an illicit substance, the prosecutor has to provide an accounting of the whereabouts of the illicit substance, from the moment of its seizure from the suspect and, throughout its custody. In this manner, the illicit substance is authenticated at the final destination, in the court, as belonging to the defendant. The probative value and the strictness with which this rule is applied are directly related to the value of the evidence and the importance associated with the unchanged condition of the evidence.<sup>126</sup> Note, however, that the burden of proof in establishing the chain of custody is relatively light: reasonable probability.<sup>127</sup>

In this metaphor, the publishing researcher, like someone presenting evidence, attests to a finding, and, by ascribing the finding to herself and her co-authors, she personally vouches to the authenticity of her findings. As subsequent researchers cite this work in their own research, they elongate the chain of custody of scientific knowledge that stretches back to the originator of the scientific finding. If this testimony is based on fraudulent foundations, because it is plagiarized, or the proper people were not acknowledged, then, like custodial negligence in evidence, the chain becomes broken and we cannot reliably authenticate the results of the experiment. Thus, like fraud and fabrication, plagiarism too might be seen as a type of misconduct that threatens to undermine the authenticity of the data.

But the metaphor breaks down (unless the evidentiary item is readily identifiable)<sup>128</sup> because, without the evidentiary chain of custody for either fungible<sup>129</sup> or laboratory analyzed evidence,<sup>130</sup> a court cannot and will not conclude that the evidence presented in court is categorically the evidence taken from the defendant or that the condition of the evidence is unchanged from its original state. In contrast, a plagiarized scientific work does not present an authenticity problem to the same extent. By definition, in finding an act of plagiarism, we definitively identify the real author, who can then authenticate the work. In evidence this is usually not possible once the chain is broken.

Still, there remains the possibility of numerous negative consequences emanating from plagiarized work, although not as certain as the consequences from a first tier type action. It may cost funding agencies a lost opportunity: where would the money have gone if not to the plagiarizing scientist who does not add anything to the body of

<sup>&</sup>lt;sup>125</sup> United States v. Ricco, 52 F.3d 58, 61-62 (4th Cir. 1995); United States v. Collado, 957 F.2d 38, 39 (1st Cir. 1992); United States v. Casto, 889 F.2d 562, 568 (5th Cir. 1989); United States v. Mendel, 746 F.2d 155, 166-67 (2d Cir. 1984).

<sup>&</sup>lt;sup>126</sup> United States v. Lampson, 627 F.2d 62, 65-66 (7th Cir. 1980).

<sup>&</sup>lt;sup>127</sup> United States v. Brown, 482 F.2d 1226, 1228 (8th Cir. 1973).

<sup>&</sup>lt;sup>128</sup> State v. Conley, 288 N.E.2d 296, 300 (Ohio Ct. App. 1971).

<sup>&</sup>lt;sup>129</sup> Paul Giannelli, *Chain of Custody and the Handling of Real Evidence*, 20 Am. Crim. L. Rev. 527, 534 (1983).

<sup>&</sup>lt;sup>130</sup> See, e.g., Robinson v. Commonwealth, 183 S.E.2d 179, 180 (Va. 1971).

scientific knowledge? Plagiarism can also potentially impact the scientist who was plagiarized,<sup>131</sup> for she may lose out on credit, honor, increased funding, or advancement due to her for her discoveries.<sup>132</sup> Notwithstanding these outcomes and the fact that plagiarism is one of the most common allegations made in the scientific community, actual misconduct is rarely found in the examination of an accusation of plagiarism.<sup>133</sup>

Second tier fraud might also include abuse of the peer review process for personal gain by either misappropriating proprietary information or delaying publication of an otherwise legitimate paper. Like plagiarism, there are limited numbers of victims in this case. Although it could be argued that given the importance and centrality of the peer review system in the scientific enterprise, any abuse of the system undermines all of science and ought to be considered a first tier offense.

<sup>132</sup> Would a definition of plagiarism include the very common and accepted co-authorship by senior professors who provided little if anything to the research, the so called "honorary plagiarism?" "Many senior scientists don't allow new graduates to take credit for their own ideas. I feel that this is a particularly insidious form of plagiarism, and it's not new." *Id.* (citing an Australian Newspaper article.). Is this type of activity, where senior officers take away some of the credit from the real authors, similar to the usual type of plagiarism? Is this even an ethical issue or one of research etiquette? *See, e.g.*, Brian Martin, *Plagiarism: A Misplaced Emphasis*, 3 J. of Info. Ethics 36 (1994) ("[C]ompetitive plagiarism is given too much attention and condemned in far too extreme terms [and] institutionalized plagiarism deserves more attention.").

<sup>133</sup> Dr. Alan Price of the Office of Research Integrity suggests some reasons why this may be the case:

(1) [T]he cases were resolved based on the evidence before reaching the level of an investigation; (2) institutional committees had difficulty determining ownership of the words or ideas of people who had worked together as collaborators, student/mentor, or investigator/co-investigator; or (3) the allegations involved such a minimal copying of words without quotation marks or complete citations that investigations were not warranted. Even in cases with significant allegations, many institutions have given reprimands without reaching findings of misconduct.

Office of Res. Integrity & Am. Assoc. for Advancement of Sci., Executive Summary of the ORI/AAAS Conference on Plagiarisms and Theft of Ideas, June 21-22, 1993, at the National Institutes of Health Lister Hill Auditorium Bethesda, Maryland 12 (Alan Price ed. 1993), *available at* http://ori.dhhs.gov/documents/aaas.pdf.

<sup>&</sup>lt;sup>131</sup> A scientist who is plagiarized, if desired, can sue in court for misappropriation of her ideas as an alternative to going through academic channels. *See, e.g.*, Eliot Marshall, *Two Former Grad Students Sue Over Alleged Misuse of Ideas*, 284 Sci. 562, 563 (1999) (Nevertheless, this is a complicated issue for a lay jury and judge: "The judge, and possibly a jury, might be asked to rule in a few days on who contributed what to a complex scientific proof – the kind of controversy that can take years to resolve among mathematicians.").

#### 3. Third Tier Fraud

A third level of fraud may include actions such as salami slicing papers, or duplicate publications.<sup>134</sup> Plagiarism involving background or methodological sections in papers would be included here as well. Other potential acts of misconduct might include claiming authorship on a paper one provided negligible work towards,<sup>135</sup> data beautification by manipulating and cleaning up images of results,<sup>136</sup> citation and quotation errors,<sup>137</sup> the misrepresentation of credentials,<sup>138</sup> and failures in either animal welfare or human subject research regulations.<sup>139</sup> While each of these third tier types of misconduct has, like the other tiers, the potential to do serious damage to the scientific infrastructure, on the whole they are relatively benign toward both the general institution of science and the validity of the underlying science. Many of Martinson's types of fraud may fit within this tier.<sup>140</sup> Still, Bruce Alberts and others raise arguments along the lines of New York Mayor Rudolph Giuliani's focus on quality of life crimes in the early 1990s: it is the lower level fraud that is the worst, as it erodes the base and will eventually, if not punished, lead to higher and more problematic levels of fraud.<sup>141</sup>

<sup>136</sup> Editorial, *Beautification and Fraud*, *supra* note 69, at 101 (noting that up to 20% of accepted papers are cleaned up); *see also* Helen Pearson, *Forensic Software Traces Tweaks to Images*, 439 Nature 520, 520-21 (2006). It should be noted that this category of misconduct should be limited to beautification that does not create or change results.

<sup>137</sup> Drenth, The Responsible Conduct of Basic and Clinical Research, *supra* note 58.

 $^{138}$  *Id.* Misrepresentation of credentials may be pervasive in science, but the numbers are not clear.

<sup>139</sup> Note that the National Science Foundation seems to exclude many of these from their definition of actionable research misconduct. *See, e.g.*, Boesz, *supra* note 113.

<sup>140</sup> See Martinson, Anderson, & de Vries, *supra* note 56, at 737.

<sup>&</sup>lt;sup>134</sup> Studies have shown that duplicate publications, estimated to be around twenty-five thousand per year, cost science up to 25 million dollars per year. Drenth, The Responsible Conduct of Basic and Clinical Research, *supra* note 58. One might argue that by inundating the body of articles with excessive publications one hurts numerous scientists who waste their time and resources wading through all of them.

<sup>&</sup>lt;sup>135</sup> Although, "most of the time misconducts regarding authorship will have no important consequences for the public's health, . . . they have an effect on the public perception on the reliability on biomedical science." Ana M. Garcia, *Sixth Version of the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals": Lots of Ethics, Some New Recommendations for Manuscript Preparation*, 58 J. Epidemiol. Cmty. Health 731, 731 (2004).

<sup>&</sup>lt;sup>141</sup> Alberts & Shine, *supra* note 18, at 1660. This is also known as the 'broken windows theory.' *See, e.g.*, James Wilson & George Kelling, *Broken Windows: The Police and Neighborhood Safety*, 249 Atlantic Monthly 29, 31 (1982); *see also* Kreutzberg, *supra* note 22, at

#### 4. Misconduct that Should Not Be Included as Fraud

Although some have suggested scientists be punished for negligent behavior,<sup>142</sup> misconduct in science should not include "errors of judgment; errors in recording, selection, or analysis of data; differences in opinions involving the interpretation of data; or misconduct unrelated to the research process,"<sup>143</sup> notwithstanding the harmful effects of negligence or sloppy science.

"Another category of behaviors—including sexual or other forms of harassment, misuse of funds, gross negligence in a person's professional activities, . . . are not necessarily associated with scientific conduct. Institutions need to discourage and respond to such behaviors. But these behaviors are subject to generally applicable legal and social penalties and should be dealt with using the same procedures that would be applied to anyone."<sup>144</sup> Nor should there be a rebuttable presumption of misconduct if records are missing; the onus should instead remain on the government to prove fraud and intent to deceive.

331, for an additional analogy to how doping in sports starts small and grows as one sees how easy it is to deceive.

142

By introducing preventable errors into science, sloppy or negligent research can do great damage—even if the error is eventually uncovered and corrected. Though science is built on the idea of peer validation and acceptance, actual replication is selective. It is not practical (or necessary) to reconstruct all the observations and theoretical constructs that go into an investigation. Researchers have to trust that previous investigators performed the work as reported. If that trust is misplaced and the previous results are inaccurate, the truth will likely emerge as problems arise in the ongoing investigation. But researchers can waste months or years of effort because of erroneous results, and public confidence in the integrity of science can be seriously undermined.

COSEPUP Report, *supra* note 6, at 16; *see also* Rebecca Dresser, *Defining Scientific Misconduct: The Relevance of Mental State*, 269 JAMA 895, 895 (1993).

<sup>143</sup> Bradshaw, *supra* note 106.

<sup>144</sup> COSEPUP Report, *supra* note 6, at 18.

Once the scientific community has decided what the metes and bounds of ethical and moral behavior are, they can be inculcated in present and future generations of scientists. Most importantly, the old guard has to accept that fraud is a real, important, and potentially pervasive issue within the scientific community; and, as such, they have to take the issue seriously, if for no other reason than to set a positive example for the next generation of scientists.<sup>146</sup>

Most commentators agree that research ethics to be taught or imparted to graduate students on some formal level,<sup>147</sup> and possibly on a continuing basis throughout their career,<sup>148</sup> although it is unclear who is best suited to impart this knowledge.<sup>149</sup>

<sup>146</sup> Drenth, The Responsible Conduct of Basic and Clinical Research, *supra* note 58 ("The majority of professional laboratory scientists are unenlightened, confused, and at times embarrassed at the revelations and counter-revelations, concerning the research culture, that have been a focus of attention in the media during the past 2 decades."); *see also* Cassidy *supra* note 6.

<sup>147</sup> But see Karen J. Maschke, What's the Professor Got to Do with It?, 2 Am. J. of Bioethics 63, 63-64 (2002). And according to Rob Schwartz,

However, we should be wary of the thought that our problem with unethical research can be solved by the creation of these courses. . . . [The] thoughtful point that "the key to doing good in science is doing science well" might suggest that the best ethical return on an educational investment would come from more or better graduate courses in statistics and epidemiology, for example, or in other areas of substantive science, rather than ethics. . . . Similarly, we might wonder how scientific research would be affected if our researchers were taught music, expository writing, time management, meditation, or how to work with colleagues more successfully. . . . Given the time demands on graduate students and the practicalities of their training, the question we need to ask is whether a formal course in research ethics is worth more than anything else those students could be doing with that same time.

Rob Schwartz, *The Professor is Excused*, 2 Am. J. of Bioethics 59, 60 (2002) (quoting Kenneth Richman, *Responsible Conduct of Research is All Well and Good*, 2 Am. J. of Bioethics 61, 61 (2002).

<sup>148</sup> See Richard Sharp, *Teaching Old Dogs New Tricks: Continuing Education in Research Ethics*, 2 Am. J. of Bioethics 55, 56 (2002).

<sup>149</sup> "Above all, however, we must do more to reach out to the scientific community—senior scientists, postdoctoral researchers and students alike—and make them more aware of the pitfalls

2009

<sup>&</sup>lt;sup>145</sup> Note the conclusions of a recent report on research integrity finding that "[t]here is a lack of evidence to definitively support any one way to approach the problem of promoting and evaluating research integrity." Comm. on Assessing Integrity in Res. Env'ts, Nat'l Res. Council & Inst. of Med., Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct 124 (2002) [hereinafter Integrity in Scientific Research].

1. Schools

#### a. Institutions

With the monetary, social, and career costs associated with fraud, not to mention the bad publicity, academic institutions have a vested interest in dealing with the issue of fraud in science long before their students become involved. Educating students, researchers, and administrators in a formal educational setting about all aspects of fraud seems to be the most efficient and cost effective way to initially deal with research misconduct. Unfortunately, universities and other schools often fail to sufficiently prepare their students with the proper degree of moral and ethical training.

Scholars note that science graduate students often lack the skills to do what is morally correct in questionable situations within the confines of science research.<sup>150</sup> Some blame this on a graduate training lacking in ethical guidance.<sup>151</sup> Others argue that, although science has not yet formalized its ethical traditions, they are passed on informally during graduate training.<sup>152</sup>

Nevertheless, many have suggested that science graduate students ought to be receiving a thorough formal ethical education in their undergraduate and/or graduate studies.<sup>153</sup> Presently, requirements for ethics courses are typically limited to graduate and

and consequences of fraud. ... [W]e need to raise awareness further." Kreutzberg, *supra* note 22, at 332.

<sup>150</sup> See, e.g., Henriikka Clarkeburn, A Test for Ethical Sensitivity in Science, 31 J. of Moral Educ. 439, 452 (2002) (noting the relatively low levels of ethical sensitivity in science students and calling for increased ethics education). But see Stanley G. Korenman et al, Evaluation of the Research Norms of Scientists and Administrators Responsible for Academic Research Integrity, 279 JAMA 41, 41 (1998) (noting that "surveyed scientists and institutional representatives had strong and similar norms of professional behavior").

<sup>151</sup> See, e.g., Robert Cowen, The Not So Hallowed Halls of Science, 86 Tech Rev. 8 (1983).

<sup>152</sup> See, e.g., Pigman & Carmichael, *supra* note 45. *But see* Integrity in Scientific Research, *supra* note 145, at 20 ("[M]uch less attention [has been devoted] . . . to the task of fostering a research environment that promotes integrity.").

<sup>153</sup> See, e.g., Integrity in Scientific Research, *supra* note 145, at 26 (noting the vital role research institutions play in providing an integrity-rich environment and citing the need for institutions to provide training, establish unambiguous policies, and provide support). The report also sees the institution as the only consistent part of a graduate education, with individual PI's differing radically. Thus "[r]esearch institutions should consistently and effectively provide training and education, policies and procedures, and tools and support systems. Institutional expectations should be unambiguous, and the consequences of one's conduct should be clear." *Id.* at 26. *But see, e.g.*, Lawrence M. Krauss, *The Citizen-Scientist's Obligation to Stand Up for Standards*, N.Y. Times, Apr. 22, 2003, at F3 ("[L]ike almost all scientists I know, I have no formal training in this subject. Indeed, like many of my colleagues, I have been reluctant to include formal courses on ethics in the physics curriculum, and I have tended to suppose that students should learn the ethos of science 'by example.'").

postdoctoral students with U.S. government funding.<sup>154</sup> Although covering most graduate students, this will not include most foreign students and postdoctoral fellows. Courses should be required for all students, post docs, and even junior faculty independent of their source of funding. Ethics courses would optimally teach scientists the reasons behind the prevailing standards of research ethics, demonstrate how to responsibly investigate any situation that may arise during the course of their careers, and inculcate the ability to independently formulate ethical responses to issues and instances that occur.<sup>155</sup> Further, unlike the current situation, schools and professors must imbue these programs with a greater sense of importance to make students more likely to view ethics as an important area of knowledge.

Given the significant time and work pressures on many graduate students, it is imperative that any research ethics course be given in a way that engages students.<sup>156</sup> Moreover, it may be beneficial to give this course early on in graduate education, even prior to starting research, not only to stress the importance of ethical conduct, but also to assure educators that students will be properly engaged in the discussion and not distracted by their work.<sup>157</sup> Unfortunately, the concept of a research ethics course is relatively new,<sup>158</sup> and as such, there may be limited resources to build upon and evaluate in constructing a course.

Still, any course that aims to introduce students to the literature, history, and issues surrounding fraud in science may still fail as a means to deter it.<sup>159</sup> Particularly, given the typical workload of a junior scientist, an ethics course may become an optimal opportunity to catch up on one's reading or sleep.<sup>160</sup> Moreover, even if instructors can

<sup>155</sup> See, e.g., Caroline Whitbeck, *Teaching Ethics to Scientists and Engineers: Moral Agents and Moral Problems*, 1 Sci. & Eng'g Ethics 229, 229 (1995).

<sup>156</sup> See Alberts & Shine, supra note 18, at 1660.

<sup>157</sup> Although it may also be helpful to require refresher courses throughout graduate training. See, e.g., Ari Eisen & Roberta M. Berry, *The Absent Professor: Why We Don't Teach Research Ethics and What to Do About It*, 2 Am. J. of Bioethics 38, 39 (2002) ("We argue that it should be formal and explicit from the beginning, and we suggest that continuing education in research ethics should become an integral part of the life of the practicing bioscientist.").

<sup>158</sup> See, e.g., Ruth Ellen Bulger & Stanley Joel Reiser, *Studying Science in the Context of Ethics*, 68 Acad. Med. S5, S6 (1993) (citing a 1984 University of Texas course as the first known course in research ethics).

<sup>159</sup> See, e.g., Kenneth D. Pimple, Assessing Student Learning in Research Ethics, 4 Trends 2B (1997), available at http://www.indiana.edu/~poynter/tre4-2b.html (describing the failure of a particular research ethics course).

<sup>160</sup> "Education in the responsible conduct of research is critical, but if not done appropriately and in a creative way, education is likely to be of only modest help and may be ineffective." Integrity in Scientific Research, *supra* note 145, at 124; *see also* Sovacool, *supra* note 12, at ¶1

<sup>&</sup>lt;sup>154</sup> See, e.g., Charles E. Deutch, A Course in Research Ethics for Graduate Students, 44 C. Teaching 56, 57 (1996).

keep a student's attention through interesting readings and the like, by the time students are exposed to the ethics courses in their curriculum they are already learning primarily from their mentor, not the classroom.<sup>161</sup> Finally, even if schools can provide proper ethical training for their graduate students, they will still probably be unable to thoroughly police their students.<sup>162</sup>

Importantly, schools must also make it clear the institution will accommodate whistleblowers in fleshing out purported fraudulent activity and maintaining privacy. Graduate students and postdoctoral fellows are particularly at risk when blowing the whistle on their mentor. If they do nothing, their findings and publications could be tainted by the fraud when accusations eventually emerge. If they charge their mentor with fraud they risk losing their job, and when the mentor is particularly prominent or supported in the academic community, they also risk their reputation if their allegations do not stand up.

#### b. Mentors

"[T]he responsibility of the senior scientist [i.e. the Principal Investigator (PI)] to maintain the integrity of science cannot be overstated."<sup>163</sup> Given the importance of the mentor relationship within the graduate education of any scientist, <sup>164</sup> it may be more beneficial for the student to learn by example from their mentor.<sup>165</sup> Unfortunately, with

("[E]ducation is likely to be only of modest help because it is often done non-creatively and implemented inappropriately.").

<sup>161</sup> Some have found ethics courses are best taught to a self-selecting, motivated group of students, not by requiring all students to take a course on research ethics. *See* Anne Koerber,

## Enhancing Ethical Behavior: Views of Students, Administrators, And Faculty, 69 J. Dental Educ. 213, 213 (2005).

<sup>162</sup> While federal regulations require schools to have policies regarding science misconduct, there are no corresponding regulations requiring prevention or even policing of their researchers. *See, e.g.*, Barbara K. Redman & Arthur L. Caplan, *Off With Their Heads: The Need to Criminalize Some Forms of Scientific Misconduct*, 33 J.L. Med. & Ethics 345, 346 (2005).

<sup>163</sup> Kreutzberg, *supra* note 22, at 331.

<sup>164</sup> See The Nat'l Acad. of Sci. et al., Adviser, Teacher, Role Model, Friend: On Being a Mentor to Students in Science And Engineering 1-2 (1997), *available at* http://newton.nap.edu/html/mentor/1.html (for a good description of the mentor/graduate student relationship.); *aee also* Rackham Sch. of Graduate Studies, Univ. of Mich., How to Mentor Graduate Students: A Guide for Faculty in a Diverse University 4 (2006), *available at* http://www.rackham.umich.edu/downloads/publications/Fmentoring.pdf.

<sup>165</sup> A mentor's "ethical, scientific, and professional behavior all leave a strong impression on students." The Nat'l Acad. of Sci. et al., *supra* note 164, at 61; *see also* Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 Geo. Mason Ind. L. Rev. 305, 315-16 (1995) ("The habits and attitudes acquired in laboratory apprenticeship form a set of internalized rules that are perhaps the best safeguard for research integrity. Internalized

. . . .

the exception of some younger mentors, most principal investigators themselves lack a basic education in research ethics.<sup>166</sup>

Moreover, even if a student's mentor has had an ethics education, many, if not most graduate students rarely have the opportunity to interact with their mentors in such a way that they can learn ethical norms and behavior.<sup>167</sup> This leaves a sizable chunk of the scientific population without ethical training.<sup>168</sup>

Even those students who will be in a position to learn some ethical conduct from their mentors will still lack a large amount of the ethical knowledge that is required for a life-long career in science. They may learn from the rare example, but will not be inculcated with a broad understanding of ethics, nor the knowledge or methodology for applying what little they do learn.<sup>169</sup>

rules are continually operative without the need for external oversight or implementation." Thus they are cheaper.)

<sup>166</sup> See, e.g., Eisen & Berry, *supra* note 157, at 42 (stating most "[f]aculty members and mentors generally have received little or no formal ethics instruction themselves").

<sup>167</sup> Eisen and Berry highlight the difficulties with having a mentor be the only source of ethical training for graduate students: "They endure numerous competing demands on their time and resources, and they are likely to be concerned that yet more demands upon them may interfere with the competitiveness of their labs." *Id.* at 42.

<sup>168</sup> *Id.* at 38 ("[A] fifth of these graduate students reported that they got *no* help in this area. Most said the help their mentors provided did not qualify as effective education in research ethics.").

<sup>169</sup> But see generally Janet Bercovitz & Maryann Feldman, Academic Entrepreneurs: Social Learning and Participation in University Technology Transfer, Proceedings, 2006, at 1, available at

http://www.hhh.umn.edu/centers/slp/clusters\_entrepreneurship/pdf/bercovitz\_academic\_entrepre neurs.pdf (noting that imprinting of social and ethical values, in their case the values related to technology transfer, is a real phenomenon in universities, particularly in the mentor to student relationship)..

[P]rofessional training can instill a particular set of norms and ideas and in acting according to these norms, students serve as a critical conduit for the diffusion of new ideas and practices. . . . [I]ndividuals who trained at institutions where participation in technology transfer was accepted and actively practiced will be more likely to adopt these practices in their own careers.

When faced with uncertainty about the proper course of action, social learning theory posits that individuals will model the behaviors of referent others. In addition to leaders . . . one's peer group acts as a relevant source of information. Numerous prior studies provide evidence learning activity occurs within a cohort of peers as individuals draw inferences about the value of alternative behaviors by observing the choices of "similar" others. For scientists, both industrial and academic, local group norms have been shown to play a significant role in determining individual behavior.

### 2. Other Institutions

"There is clearly a role for scientific societies to play in influencing the moral tone and ethical climate in which research is conducted."<sup>170</sup> The scientific society is typically a long-term public institution, often highly visible both within the scientific community and to the public at large.<sup>171</sup> Societies, as appointed representatives of a particular scientific community, ought to have the moral authority to teach and impose ethical standards upon their members.<sup>172</sup> Societies also typically tend to be more democratic than other scientific institutions, allowing individual members a say in the debate and development of moral standards. Finally, societies ought to have a vested interest in teaching ethics to their members, as fraud reflects poorly on the subspecialty that they represent, not only because of the fraud itself, but also because of the inability of the community to discover the fraud. Funding agencies also have a vested interest in educating their grant recipients: fraud is a waste of their resources that could have been better used elsewhere. Both funding agencies and scientific societies can be more involved in enhancing the ethical education of science researchers, potentially through creating websites that inform researchers,<sup>173</sup> and by providing public forums and conferences for discussion and debate. Funding agencies should require those who receive funding to have ongoing ethical training – potentially even certification, or some form of continuing ethical education requirement, not just the typical one course prerequisite.

Journals should also be involved in developing standards;<sup>174</sup> they too look bad when fraud is discovered in their issues because it reflects poorly on their ability to screen and weed out bad papers. Still, they should be careful to not stray too far from standards accepted by science in general.<sup>175</sup> Given their relative autonomy and their

*Id.* at 8, 11 (citations omitted); *see also* Kreutzberg, *supra* note 22, at 331 (referring to the *cosi fan tutti* effect of seeing how peers and mentors deal with ethical situations).

<sup>170</sup> Frankel, *supra* note 11, at 216 (noting that there are a number of societies that distribute information regarding science misconduct). *see, e.g.*, Am. Soc'y of Microbiology (ASM), Code of Ethics (2000), *available at* http://www.asm.org/general.asp?bid=14777.

<sup>171</sup> Frankel, *supra* note 11, at 217.

<sup>172</sup> Journals are also often associated with a specific society, giving the society more leverage to teach and possibly enforce ethical norms and behavior.

<sup>173</sup> E.g., Nat'l Inst. of Health, Bioethics Resources on the Web, http://www.nih.gov/sigs/bioethics/ (last visited Jan. 28, 2009).

<sup>174</sup> See, e.g., Vancouver Guidelines, *supra* note 110; *see also* Garcia, *supra* note 135, at 731 ("More than a half [of the guidelines are] devoted to ethical principles related to the process of evaluating and publishing manuscripts in biomedical journals and the relationships between editors, authors, peer reviewers, advertisers, and the media.").

<sup>175</sup> See, e.g., Garcia *supra* note 135, at 731 (finding that journals may create unnecessary and marginalized ethical requirements). "In a survey of 66 researchers from a university medical faculty in Britain—half of them with more than 30 published papers—only five respondents were

absolute control over what gets published, editors may go too far in establishing the bounds of fraud that encompass too much or too little.

#### 3. Journals

In the Letters section of the June 20, 2008 issue of *Science Magazine*,<sup>176</sup> the authors describe a Hippocratic-style oath taken by graduating life science doctoral students at the University of Toronto. Unlike others who support oaths requiring budding scientists to refrain from research that could potentially ever harm humanity<sup>177</sup> – notwithstanding the fact that scientists are not trained to make such a distinction, nor should they be – the University of Toronto's oath focuses on the immediate and the relevant; scientific misconduct. Although admirable, the oath remains mere window dressing without proper follow up. As graduate students go out into the world and continue to experience the demands and burdens of a career, this oath might soon become a distant memory.

Perhaps the next step following the institution of an oath is a continuing educational requirement akin to the attorney's CLE or the physician's CME. But unlike many other professions that take oaths, life science researchers are not licensed by any particular agency, and lack the requisite continuing education requirements that are integral to licensure.

Consequently, instead of a bar or a board enforcing continuing education, scientific journals could require continuing educational credit as a requisite for publishing. Without a specified number of class hours of, for example, ethics, relevant regulations, or writing classes, a scientist would be unable to publish her work. While the immediate result might be a haphazard Balkanized system of varied requirements for different journals, the market would quickly sort out the number and types of courses required, creating a relatively universal and manageable requirement-set across all journals.

Although non-trivial to implement, a system of continuing education that focuses on many of the often overlooked components of a graduate education, particularly issues of scientific misconduct, would not only help to prevent future instances of misconduct, but might also reinvigorate the stagnant US science budget by reassuring an already skeptical public that federally funded research is not, as the media might suggest, awash in scientific fraud.

able to quote all three criteria of the ICMJE for authorship, and only one knew that all three criteria were required to credit authorship." *Id.* 

<sup>&</sup>lt;sup>176</sup> Karen Davis et al., A Graduate Student Oath, 320 Sci. 1587, 1587-88 (2008).

<sup>&</sup>lt;sup>177</sup> Rotblat, *supra* note 5, at 1475.

#### D. Enforcement

"The problems arise when there is no authority or the authority doesn't see it as its task to investigate."<sup>178</sup>

#### 1. Due Process

Given that a scientist's career is typically at stake when he is accused of misconduct and fraud, it is imperative that any investigation be impartial and thorough.<sup>179</sup> Accusations of fraud are exacerbated by the fact that the researcher in question is not the only person who stands to lose in a misconduct investigation. The greater community of scientists can all be negatively affected by a single infamous case of scientific fraud. Although there should not be any particular set of rigid due process guidelines for scientific misconduct inquiries,<sup>180</sup> there are a number of procedural aspects that should be universally upheld in such an inquiry whether it is a civil, criminal, or internal investigation.<sup>181</sup>

Thus even if scientists disagree about the extent of a problem and its solutions, all should be in agreement that whatever the problem is, it ought to be fixed quickly to minimize the negative impact on science.<sup>182</sup> Similarly, it is important that the process towards guilt or exoneration be free of overburdening complications, for all parties involved, so that potential chilling effects related to the process are limited, and that all decisions be accompanied by written reasons.<sup>183</sup>

Independent of the enforcing institution or mechanism, it is important, first and foremost, that exceptional care be taken to make sure that there is due process given to

<sup>179</sup> And fast: "justice deferred is justice denied." Donald Kennedy, *In Science Fraud Case, Justice Is Denied*, N.Y. Times, June 24, 1996, at A14 (commenting on the *New York Times*' poor coverage of the David Baltimore case).

<sup>180</sup> Goss v. Lopez, 419 U.S. 565, 578 (1975) ("[T]he very nature of due process negates any concept of inflexible procedures universally applicable to every imaginable situation.").

<sup>181</sup> Unfortunately, currently "there is good reason to believe that most personnel within the scientific misconduct bureaucracy—lawyers included—have little sensitivity to possible Fourth Amendment—or other constitutional—restraints on scientific misconduct processes." Roy G. Spece, Jr. & John J. Marchalonis, *Fourth Amendment Restrictions on Scientific Misconduct Proceedings at Public Universities*, 11 Health Matrix 571, 572 (2001).

<sup>182</sup> Note also that a fast inquiry is an important component of a thorough purging of the offending work from the scientific literature. As long as the inquiry is quick, it remains on the radar of the editors of the relevant journals. A slow and plodding process, on the other hand, threatens to become irrelevant, particularly if the affected journals get new editors who are unaware of the investigation. *See, e.g.*, Unger & Couzin, *supra* note 114, at 39-40.

<sup>183</sup> Black v. Romano, 471 U.S. 606, 618 (1985).

<sup>&</sup>lt;sup>178</sup> Jane Smith & Fiona Godlee, *Investigating Allegations of Scientific Misconduct*, 331 Brit. Med. J. 245, 245 (2005).

the suspected scientist, i.e., fair proceedings.<sup>184</sup> Although the Fourth Circuit has affirmed that "to the extent that a government agency is performing an investigative as opposed to adjudicative function, it is not affecting legal rights and an individual is not entitled to the protections usually associated with the judicial process,"<sup>185</sup> arguably due process ought to still apply in many investigations of scientific misconduct, particularly given the potential for career-destroying outcomes. Procedural due process imposes constraints on governmental decisions which deprive individuals of "liberty" or "property" interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment. <sup>186</sup> Here, governmental actors would include not only federal funding agencies and officials at state schools, but potentially even private institutions.<sup>187</sup>

Enforcement could require some form of punishment. Depending on the nature of the fraudulent act, the intentions and method of the perpetrator, and the nature of the effect on either actual victims, or on the general reputation of scientists, one could imagine a range of punishments from a simple reprimand, or restrictions on rewards and grants, to grant termination, public "disbarment," or even civil fines and imprisonment.<sup>188</sup>

The government or an independent group could even set up a Megan's Law type website that would geographically track all of those who were found to have conducted some sort of fraudulent activity. With this sort of public shaming that ties the researcher to a geographic location or even a particular institution, universities and research institutions, both public and private, may be unwilling to hire someone who has committed some form of fraud.

<sup>&</sup>lt;sup>184</sup> "I will admit with you, sir, the absence of any sense of what due process should be when some suspicion is aroused. We have never adopted standardized procedures of any kind to deal with these isolated events. We have no courts, not sets of courts, no understandings among ourselves as to how any one such incident shall be treated." Dr. Philip Handler, President of the Nat'l Acad. of Sci., Testimony before the Congressional Subcomm. on Investigations on Oversight, (Mar. 31-Apr. 1, 1981) *in* David J. Miller, Research Fraud in the Behavioral and Biomedical Sciences 77 (David J. Miller & Michel Hersen eds., 1992).

<sup>&</sup>lt;sup>185</sup> Popovic v. United States, 997 F. Supp. 672, 678 (D. Md. 1998), aff'd, 175 F.3d 1015 (4th Cir. 1999).

<sup>&</sup>lt;sup>186</sup> Mathews v. Eldridge, 424 U.S. 319, 332 (1976).

<sup>&</sup>lt;sup>187</sup> Spece & Marchalonis, *supra* note 181, at 574.

<sup>&</sup>lt;sup>188</sup> Editorial, *PhD* — *Club Or History*, 429 Nature 789, 789 (2004) (commenting on the University of Konstanz's withdrawal of Jan Hendrik Schon's Ph.D. after he was found to have been fabricating data).

#### 2. Self-policing

"[T]he right to self-regulation is not sacred. . . . It must be earned by showing the public that we are ensuring that research is being carried out in full honesty."  $^{189}$ 

There is a pervasive fear in science that attempted regulation by an outside source will have a deleterious effect on research and general morale.<sup>190</sup> Vannevar Bush expressed this in his seminal work, *Science The Endless Frontier*, the guidebook for much of the government's involvement in science research for the past half century.<sup>191</sup> Science researchers have always operated under their own amorphous honor code. Buttressed by professional responsibility and a general reverence for science, science misconduct, when apparent, was treated rather harshly and internally. A scientist's career was essentially destroyed when her trustworthiness and reliability were called into question. While ill defined, the ethics regarding fraud were clear enough to the relevant internal community: data fabrication and falsification are not good for anyone in science, given the significant reliance on trust among peers. Even still, there were no formal methods for dealing with fraud.<sup>192</sup>

This provincial system did have some limitations: internationally, in addition to the language and legal barriers, the lack of formal methods is exacerbated by the lack of common, universally agreed upon definitions or standards, the inability for local bodies to thoroughly investigate other institutions without personal relationships or some form of agreement, and cultural differences that may blur the lines between corruption and community standards.

While not without faults, self-policing may still be the best option. It is important for scientists to be the ones to judge their peers, especially to prevent the widening of the already expansive gulf of mistrust between science and the law. Thus, while historically somewhat ineffective, self-policing can still be re-jiggered to work better.

191

The publicly and privately supported colleges, universities, and research institutes are the centers of basic research. They are the wellsprings of knowledge and understanding. As long as they are vigorous and healthy and their scientists are free to pursue the truth wherever it may lead, there will be a flow of new scientific knowledge to those who can apply it to practical problems in Government, in industry, or elsewhere. The history of medical science teaches clearly the supreme importance of affording the prepared mind complete freedom for the exercise of initiative.

Vannevar Bush, Science The Endless Frontier 12 (1945).

<sup>&</sup>lt;sup>189</sup> Abbott, *supra* note 40, at 13 (quoting Bruno Zimmermann, Head of Research Affairs at the Deutsche Forschungsgemeinschaft, Germany's main grants agency); *see also* Frankel, *supra* note 11, at 216 (noting that the professional autonomy customarily granted to science is a privilege granted by society that could easily be taken away).

<sup>&</sup>lt;sup>190</sup> See, e.g., literature cited supra note 18.

<sup>&</sup>lt;sup>192</sup> See, e.g., Baltimore, supra note 3, at 290.

One of the main strengths and weaknesses of the self-policing mechanism has been the peer review system. Peer review has weakened in its effectiveness over time, mostly because it is viewed as a burden, particularly by more senior scientists, rather than an integral component of the scientific enterprise. Older researchers often hand off the responsibility to younger and inexperienced graduate students to peer review in their name. The anonymity of the system allows these senior scientists to have their reviews ghostwritten, protecting them from the embarrassment of a poor or ineffectual review written without regard for the importance of the institution. Alternatives to the present system, including co-opting methods used in e-commerce sites such as Amazon to promote voluntary reviews by non-anonymous peers,<sup>193</sup> might be a helpful step in reviving the status, importance, and effectiveness of peer review.

The two most prominent actors in self-policing academic scientists are the institutions for which they work and the journals where they publish.

### a. Universities

Outside of this blatant conflict of interest between publicly punishing misconduct and the need to maintain a scholarly reputation, one pervasive practical problem with institutions policing themselves is that, given the rarity of science misconduct tribunals in academia, the scientists involved in judging their peers will most likely be novices at doing so and potentially biased or even unwilling to believe that fraud has occurred, as it goes against their basic understanding of science and the Mertonian idealized institution of science.<sup>194</sup>

Even with these aforementioned issues, it is important, nevertheless, that the primary investigation occur at the institutional level, as only here, away from the public eye, can the accused be protected from what could destroy her career even if she is exonerated. While in-house investigations are a potentially enormous burden for the institution and all those involved,<sup>195</sup> the alternative is a public disclosure that neither the accused, nor the institution really wants. One possible solution is to create a semi-permanent panel,<sup>196</sup> one with well-respected academics in each institution to act as

<sup>196</sup> Using semi-retired academics might be an advantage here, because investigations are time consuming.

<sup>&</sup>lt;sup>193</sup> Dov Greenbaum, Joanna Lim, & Mark Gerstein, *supra* note 2, at 296-97.

<sup>&</sup>lt;sup>194</sup> See, e.g., Kreutzberg, supra note 22, at 330.

<sup>&</sup>lt;sup>195</sup> "The toll it takes is enormous. . . . People get wrapped up in these cases for years. They have told me they couldn't afford to do it again; it destroys their careers." Abbott, *supra* note 40, at 14 (quoting William R. Brinkley, a dean at Baylor College of Medicine in Houston, Texas, and president of the Federation of American Societies of Experimental Biology (FASEB) commenting on an inquiry that took place in his institution). *See also generally* Unger & Couzin, *supra* note 114.

judges,<sup>197</sup> and potentially even punish the accused. Such a panel should be encouraged to have an extensive, but relatively quick review of the issues, even preceding any full-scale investigation with an informal analysis as to whether the case merits further investigation. An appellate process could be either internal, through the courts, or some sort of binding arbitration.

Alternatively, regional panels, filled primarily with semi-retired or emeriti scientists, and akin to U.S. federal circuit courts, could be set up to judge and police a number of geographically linked schools; these panels would be more likely to be experienced and knowledgeable.

#### b. Journals

With publications being the currency of a scientist's career, one would think that journals would be a prime gatekeeper for fraudulent activity.<sup>198</sup> A journal could police simply and easily by a limited investigation into the fraud, followed by a retraction of the fraudulent papers.<sup>199</sup> With the possibility for the journal to simply retract the suspected work without publicly accusing the scientist of fraud, coupled with the ability for that scientist to appeal the decision, journals could avoid many of the concerns that necessitate an expansive due process system.<sup>200</sup>

Scientists may engage in all types of fraud for whatever reason, but independent of the impetus for fraud, they are often comforted by the fact that they will most likely never be caught, and even if they are caught, they face few if any repercussions for most forms of fraud. Thus, it is important for journals to get involved in enforcing some sort of punishment as well, although following the proposed tiered system: when fabricated and falsified data results in a publication, that publication must be fully retracted. <sup>201</sup> The

<sup>198</sup> See, e.g., Unger & Couzin, *supra* note 114, at 43 (quoting Harry Klee, the editor of *The Plant Journal*, as stating that a journal should be the "primary point of enforcement" against fraud, and noting that this view is not widely shared by other editors); *see also* Ljiljana Vuckovic-Dekic, *Role of Journals in Addressing Scientific Misconduct*, 45 Croat. Med. J. 104, 104 (2004).

<sup>199</sup> This would seem to be the limit of their ability to police. *See, e.g.*, Emma Marris, *Should Journals Police Scientific Fraud?*, 439 Nature 520, 520 (2006).

<sup>200</sup> See, e.g., infra notes 294-313 and associated text.

<sup>201</sup> Alison Abbott & Johanna Schwarz, *Dubious Data Remain in Print Two Years after Misconduct Inquiry*, 418 Nature 113, 113 (2002).

<sup>&</sup>lt;sup>197</sup> Some might argue that even within academia, different disciplines need to be judged differently. *See, e.g.*, Alison Abbott, *Social Scientists Call for Abolition of Dishonesty Committee*,

<sup>421</sup> Nature 681, 681 (2003) ("[M]any social scientists think that his book should not be judged by criteria used to assess dishonesty in the natural and medical sciences.").

journal should also retract plagiarized papers. Importantly, even lower-tiered fraud that does not affect the veracity of the paper ought to be acknowledged somehow on the electronic record of that publication. The notation doesn't have to be permanent and can be removed after a set number of years. Such a notation, a blight on any curriculum vitae, can serve as a strong deterrent against fraudulent activity. Journals should publish regularly on cases of fraud, or run articles related to fraud – so that the ideas are constantly in the mind of the researcher. A recent report in *Nature* noted that, "[e]ven papers that investigators have found fraudulent can linger in the scientific record for years."<sup>202</sup> Journals have to determine the optimal method for notifying scientists of retracted papers, possibly even sending information about the retraction to other authors who cite the retracted paper. Journals, by making it easier to publish contrary findings or findings that show negative results, can help bring questionable and fraudulent papers to light.<sup>203</sup>

Surprisingly, though, a recent survey of the Committee on Publication Ethics (COPE) noted that of those journals surveyed, nearly two-thirds have no policy for dealing with research misconduct.<sup>204</sup> Journals can provide numerous possible rationalizations for these lapses, including the typical: fraud in research is rare and can be dealt with on a case-by-case basis.<sup>205</sup> Or, that the journals are afraid of potential lawsuits

Scientific leaders and misconduct investigators around the world have long complained that, even when scientific misconduct is proven, no reliable mechanisms exist to remove bad information from the literature. . . .

"Somebody must be responsible for informing the journals if papers have been found to contain wrong data . . . . And the journals must find ways to alert the community."

Id. (quoting Gerhard Neuweiler, former president of Germany's science council).

<sup>202</sup> Unger & Couzin, *supra* note 114, at 40-41 (noting that fraudulent papers that remain in the literature continue to get cited, but suggesting that a cost benefit analysis would find that it may not be worth dealing with significantly older papers).

<sup>203</sup> Thomas DeCoursey, *It's Difficult to Publish Contradictory Findings*, 439 Nature 784, 784 (2006).

<sup>204</sup> Journals Winging It on Good Conduct, 311 Sci. 1687, 1687 (2006). The journals surveyed were weak on a number of fronts.

<sup>205</sup> See David Goodstein, Scientific Misconduct, Academe, Jan.- Feb. 2002, at 28, 28-29.

Serious misconduct, such as faking data, is rare. When it does occur, it is almost always in the biomedical sciences . . . . Science is self-correcting, in the sense that a falsehood . . . will eventually be discovered and rejected. . . . Still, active measures to protect science are needed, because if the record became badly contaminated by fraudulent results, it would no longer be self-correcting.

*Id.; see also* Chubin, *supra* note 43, at 177 ("Scientific institutions tend to treat each detected misdeed as an isolated incident with no general implications . . . . "); Michael Hagmann, *Scientific* 

for defamation or breach of contract if they police research fraud.<sup>206</sup> Notwithstanding these justifications, journals are failing in their gate-keeping functions, and are potentially allowing bad data into the science commons.<sup>207</sup>

Unfortunately, and contrary to conventional wisdom, journals tend not to be good gatekeepers.<sup>208</sup> Given the lack of infrastructure and resources of most journals, they are not good candidates for preventing fraud in research. Journals tend to have "patchy staffing and funding," which makes looking for fraud "an astronomically expensive and difficult thing." <sup>209</sup>

The present state of authorship further confounds a journal's ability to police fraud. With large multi-authored papers, it is difficult to discern who is responsible for the actual fraud. And, given the multidisciplinary nature of much collaboration these days, where papers are cobbled together from multiple distinct disciplines, it would seem inequitable to hold all authors responsible, particularly when they probably have nothing to do with the actual fraudulent science. To hold every author on a paper responsible for fraud would have a significant, chilling effect on collaborations, particularly crossdisciplinary and long distance collaborations, where it is difficult for every author to confirm that everything was done above board.

Additionally, journals—in the classical sense of reputable bound periodicals—are slowly losing whatever gatekeeper capabilities they once had. Increasingly scientists are choosing to publish in a number of alternative venues, including<sup>210</sup> online journal

*Misconduct: Europe Stresses Prevention Rather Than Cure*, 286 Sci. 2258 (1999) ("A lot of [U.K. researchers] thought that this only happens in other countries.") (quoting the former editor of the *British Medical Journal*); Daniel Koshland, *Fraud in Science*, 235 Sci. 141, 141 (1987) (stating that 99.9999 percent of the research presented in journals is accurate and truthful); Eliot

Marshall, *How Prevalent Is Fraud? That's a Million-Dollar Question*, 290 Sci. 5497, 5498 (2000) ("There is a 'troubling discrepancy between public statements about how 'rare' misconduct in research supposedly is and the more private belief on the part of many researchers that it is fairly common.") (quoting Nicholas Steneck); Cherry Murray & Saswato Das, *The Price of Scientific Freedom*, 2 Nature Materials 204, 204 (2003) (noting that there has only been one instance of fraud in the seventy-seven years of Bell Labs' existence)..

<sup>206</sup> See, e.g., Unger & Couzin, supra note 114, at 42.

<sup>207</sup> See, e.g., Fiona Godlee, *Dealing with Editorial Misconduct*, 329 Brit. Med. J. 1301, 1302 (2004) (noting that "[e]ditors have no mandate, and usually inadequate resources, to investigate [cases of fraud] themselves" and, as such, calling for the development of a code of ethics for journal editors); see also Smith & Godlee, supra note 178, at 245 (noting that editors do not have the ability to thoroughly investigate fraud and leave that responsibility primarily to the institutions).

<sup>208</sup> See, e.g., Unger & Couzin, supra note 114, at 38.

<sup>209</sup> Marris, *supra* note 199, at 521.

<sup>210</sup> See, e.g., Greenbaum, supra note 2, at 293.

archives,<sup>211</sup> their own online databases,<sup>212</sup> and other gray area publishing.<sup>213</sup> As selective and professionally edited journals continue to lose their monopoly of control over scientific publishing,<sup>214</sup> they also lose their limited ability to continue to act as a major checkpoint into the science information commons. Even if a journal was to retract a fraudulent paper, the author could publish it herself, or elsewhere,<sup>215</sup> with little, if any, bias against her. It then falls to the indexing services, primarily Medline,<sup>216</sup> Pubmed,<sup>217</sup> and ISI's Web of Science,<sup>218</sup> to be somewhat responsible and to annotate or remove those articles in their databases which are known to be fraudulent or have been retracted.

Notwithstanding these harsh realities for the publishing world, many journals are nevertheless working toward technologies that increase their ability to expose fraud within their publications, including plagiarism<sup>219</sup> and image manipulation.<sup>220</sup> The ability of journals to more easily and conclusively ferret out fraud is expected to grow as technology develops.<sup>221</sup> Nonetheless, "[u]ltimately, if a journal does uncover evidence of

<sup>213</sup> Ana Maria Ramalho Correia & Migeul de Castro Neto, *The Role of Eprint Archives in the* Access to, and Dissemination of, Scientific Grey Literature: LIZA - A Case Study by the National Library of Portugal, 28 J. of Info. Sci. 231, 231 (2002).

<sup>214</sup> See, e.g., Greenbaum, supra note 2, at 293.

<sup>215</sup> This is possible because journals are not very good at retracting papers, or at publicizing the retraction. *See* Unger & Couzin, *supra* note 114, at 38.

<sup>216</sup> United States National Library of Medicine, http://www.nlm.nih.gov/ (last visited Jan. 28, 2009).

<sup>217</sup> PubMed, http://www.ncbi.nlm.nih.gov/sites/entrez (last visited Jan. 29, 2009).

<sup>218</sup> ISI Web of Knowledge, http://apps.isiknowledge.com/ (last visited Jan. 28, 2009).

<sup>219</sup> Jim Giles, *supra* note 121, at 258.

<sup>220</sup> See, e.g., Pearson, *supra* note 136, at 520.

<sup>221</sup> Marris, *supra* note 199, at 520-21.

<sup>&</sup>lt;sup>211</sup> See most prominently arXiv.org, developed by Paul Ginsparg primarily for physics. Also, Harold Varmus, Director of the U.S. National Institutes of Health, attempted to create a central depository for both articles and data. And clinmed.netprints.org is "an electronic archive where authors can post their research into clinical medicine and health before, during, or after peer review by other agencies." Tony Delamothe et al, *Netprints: The Next Phase in the Evolution of Biomedical Publishing*, 319 Brit. Med. J. 1515, 1515 (1999).

<sup>&</sup>lt;sup>212</sup>See, e.g., Mark Gerstein & Jochen Junker, *Blurring the Boundaries between Scientific* '*Papers' and Biological Databases, in* Nature Y.B. of Sci. & Tech. 210, 210-12 (Declan Butler ed., 2002).

fraud, it has to rely on the researchers' institution or funding agency to investigate fully," given the lack of resources at the journal.<sup>222</sup>

Unfortunately it would appear that, given the rash of fraudulent activities within the science community, self-enforcement no longer works, at least to act as a deterrent to prevent fraud and misconduct. It is not entirely clear why this is the case.<sup>223</sup>

#### 3. Funding Agencies

Once upon a time, a failure to screen out fabricated research was a problem only for other scientists . . . . However, . . . when scientists must account for public funding of research [the public will] demand stringent screening for falsified data that absorb dollars . . . from outside of science to remedy real or perceived inadequacies in the internal policing of science.<sup>224</sup>

Presently funding agencies, such as the National Institutes of Health, take some responsibility for the teaching of research ethics within the research community through ethical education requirements in their training grants and providing some general guidance on issues such as conflicts of interest, authorship, and policies for data sharing and handling of human and animal test subjects.<sup>225</sup> Funding agencies also are involved somewhat in policing their grantees, meting out a range of punishments for misconduct in science.<sup>226</sup> However, funding agencies typically act on information provided to them by

<sup>222</sup> *Id.* at 521.

<sup>223</sup> See Stankovic, supra note 95, at 1008-09. But see Walter & Richards, supra note 57, at 142 (arguing that self-governance "creates a flourishing environment for desperados eager to profit from their misconduct and for zealots--idealists or opportunists, depending on your point of view--to don their white hats, join with government and enact Draconian measures" – a set of circumstances that "usually catches more naive innocents than street-smart desperados").

<sup>224</sup> Burk, *supra* note 165, at 319.

<sup>225</sup> Sally Rockey, Deputy Dir. Office of Extramural Res., Nat'l Inst. of Health, Integrating Integrity into the Research Process through Training, Presentation at the ESF-ORI First World Conference on Research Integrity: Fostering Responsible Research (Sept. 16-19, 2007).

<sup>226</sup> Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Servs., Publ'n No. 99-8, NIH Grants Policy Statement II-16 (1998), *available at* http://grants.nih.gov/grants/policy/nihgps/nih\_gps.pdf.

A finding of misconduct in science may result in a range of possible sanctions by NIH, including, but not limited to, withdrawal of approval of the PI or other key personnel, debarment, disallowance of costs associated with the invalid or unreliable research, withholding of all or part of a continuation award, and/or suspension or termination, in whole or in part, of the current award. the principle investigations conducted by the home institutions, rarely conducting their own investigations.

Many funding agencies may also be too large to effectively police their grantees. The National Institutes of Health, in addition to their 6,000-plus intramural scientists, has 50,000 active grants worldwide supporting more than 325,000 researchers in over 3,000 institutions.<sup>227</sup>

## 4. Government Enforcement

While including the federal government and the courts may be necessary to effectively police science, it is disliked by many within the science community, <sup>228</sup> given concerns that government actions and investigations may be based on inaccurate or inapplicable premises and, as such, will be misguided.<sup>229</sup>

#### a. Congress

The government's direct involvement in scientific misconduct officially and publicly began with Senator Al Gore's subcommittee hearings in 1981.<sup>230</sup> The intrusion into the internal affairs of the science community was, and continues to be, unappreciated

### Id.

<sup>227</sup> NIH – Overview, *available at* http://www.nih.gov/about/NIHoverview.html (last visited February 1, 2009).

<sup>228</sup> See, e.g., Baltimore supra note 3, at 290 (noting that "the cost of discovering fraud is clearly more than the price tag of the fraudulent work, never mind that the process of discovery is erosive of trust and disruptive of the effective course of science"). Professor Baltimore brings a First Amendment argument against the intrusion of the government in the policing of fraud. He notes that science is an ongoing debate that is protected by the Freedom of Speech; and like any marketplace of ideas, truth will emerge if the debate is allowed to proceed according to its inherent market forces; any hindrance to these forces will interrupt and impede the debate. Baltimore extends this concept to scientific experiments as well: experiments, integral to the scientific process, are a core component of the general sciencific discussion.. Then, he notes that the government law is that speech, whether verbal or in the form of symbolic conduct, cannot be suppressed either because society finds its content offensive or disagreeable or because it fears its potential misuse." *Id.* at 296 (quoting Natasha Lisman, *Freedom of Scientific Research: A Frontier Issue in First Amendment Law*, Boston B. J., Nov.-Dec. 1991, at 4, 6-7).

<sup>229</sup> *Id.* at 291 ("The criteria that laypeople, especially politicians, might apply to science are likely to be wrongly focused because they will be evaluating science by myths rather than realities.").

<sup>230</sup> Marcel C. LaFollette, *The Politics of Research Misconduct: Congressional Oversight, Universities, and Science,* 65 J. of Higher Educ. 261, 271-72 (1994). by the scientific community.<sup>231</sup> "There is absolutely no good reason why a Congressional subcommittee should be doing a job that scientists can and should do themselves."<sup>232</sup> Moreover, congressional hearings and actions against scientific fraud are seen by many scientists as a foray into something that the representatives know little, if anything, about. Al Gore's congressional hearings were widely perceived, derogatorily, as "an ambitious Congressman using his power to decide what is true or false in science."<sup>233</sup>

After years of congressional interest in fraud and misconduct in research, the Office of Scientific Integrity,<sup>234</sup> later renamed the Office of Research Integrity (ORI), <sup>235</sup> was established as an effort to remove the responsibility of misconduct oversight from the auspices of the funding agencies.<sup>236</sup> In addition to ORI, the government continued to act to prevent and deal with science fraud through the Commission on Research

<sup>232</sup> Dingell, *supra* note 76, at A14.

<sup>233</sup> Anthony Lewis, Abroad at Home, Tale of a Bully, N.Y. Times, June 24, 1996, at A1.

<sup>234</sup> Ironically it is named along the same lines as Orwell's government ministries in his novel *1984*. Gina Kolata, *Inquiry Lacking Due Process*, N.Y. Times, June 25, 1996, at C3.

<sup>235</sup> The Office of Research Integrity's website states that:

[ORI] promotes integrity in biomedical and behavioral research supported by the U.S. Public Health Service (PHS) . . . [and] monitors institutional investigations of research misconduct and facilitates the responsible conduct of research (RCR) through educational, preventive, and regulatory activities. [ORI is involved in] developing policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research; reviewing and monitoring research misconduct investigations . . . recommending research misconduct findings and administrative actions to the Assistant Secretary for Health for decision, subject to appeal implementing activities and programs to teach the responsible conduct of research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct; providing technical assistance to institutions that respond to allegations of research misconduct . . . conducting policy analyses, . . . administering programs for whistleblowers.

Welcome to the Office of Research Integrity, http://ori.dhhs.gov/ (last visited Oct. 31, 2008).

<sup>236</sup> This transfer of power was finalized by President Clinton's signing of the NIH Revitalization Act of 1993. About ORI – History, http://ori.dhhs.gov/about/history.shtml (last visited Oct. 31, 2008).

<sup>&</sup>lt;sup>231</sup> See, e.g., Baltimore, *supra* note 3, at 284 ("For the last six years I have personally been involved in a controversy that would have been a minor event were it not for the involvement of the political world.").

ORI has been attacked and maligned since its inception. According to the Office of Management and Budget, ORI exceeded its mandate (as defined in section 493 of the Public Health Services Act) by dealing with science fraud and science misconduct.<sup>239</sup> ORI is also frequently overruled by the Departmental Appeals Board—indicating serious concerns with ORI's methods.<sup>240</sup>

ORI lost much of its limited respect among scientists early on it its history.<sup>241</sup> After its performance in the David Baltimore scandal, it was widely perceived that ORI either "framed an innocent person, or simply failed to argue its case effectively, [but] there is no doubt that it turned in an awful performance."<sup>242</sup>

ORI was a failure partially because it lacked due process: there were no formal notices of hearing requirements, no explanations for their charges of misconduct; nor did it provide defendants with a summary of their rights, a list of witnesses, or the right to cross examine.<sup>243</sup> In 1999, ORI was stripped of its policing aspects and was reassigned to teach universities how to prevent misconduct and fraud in scientific research.<sup>244</sup>

ORI has attempted to regain its standing within the scientific community through significant revisions to its policies.<sup>245</sup> While not yet tested thoroughly, there is at least an appreciation within the community for the attempt at making up for its earlier failures.<sup>246</sup>

<sup>237</sup> Id.

<sup>238</sup> Id.

<sup>239</sup> See Daniel Goldberg, Research Fraud: A Sui Generis Problem Demands a Sui Generis Solution (Plus a Little Due Process), 20 T. M. Cooley L. Rev. 47, 61 (2003) (noting that there are obvious dangers in equipping a new agency with powers over a new and ill-defined violation: science misconduct).

<sup>240</sup> *Id.* at 63.

<sup>241</sup> *Id.* at 58 (arguing that ORI, through its actions, has shown that it is "deeply flawed both in process and result").

<sup>242</sup> Lewis, *supra* note 233, at A1.

<sup>243</sup> See Sovacool, supra note 12 W1 ("In short, almost all of the elements of due process are missing in ORI investigations." (quoting Elizabeth Howard)).

<sup>244</sup> Jocelyn Kaiser, Shalala Takes Watchdog Office out of the Hunt, 286 Sci. 883, 883 (1999).

<sup>245</sup> See Public Health Service Policies on Research Misconduct, 70 Fed. Reg. 28,369, 28,369-28,400 (May 17, 2005) (to be codified at 42 C.F.R. pts. 50, 93).

110

<sup>246</sup> See, e.g., Donald Kennedy, Praise, for a Change, 304 Sci. 1077, 1077 (2004).

#### b. Civil Actions

Civil actions can be brought against researchers who commit a broad range of science-related misconduct and fraud under the False Claims Act (FCA).<sup>247</sup> The FCA, however, may be too broad to adequately deal with scientific misconduct, <sup>248</sup> and often the amount in controversy would not be worth the government's efforts to pursue.<sup>249</sup>

Under the FCA, there is a wide range of potential plaintiffs that can bring suit, <sup>250</sup> including government employees who learn of misconduct through their duties.<sup>251</sup> The only real limitations on plaintiffs, or "relators," in the language of the Act, are that they be an original source of the information, even if they were part of the fraudulent activity themselves. Because a potential relator is in competition with everyone else for the opportunity to act as the plaintiff, a lab worker with information may be unwilling to share that information with university administrators, who could deal with the issue more effectively and internally, as administrators themselves could become a plaintiff in the case, taking away the whistleblower's monetary gains granted under the Act.

In the last quarter century, Congress has further increased the incentives<sup>252</sup> to become a plaintiff in FCA cases.<sup>253</sup> Congress has also authorized courts to increase the

<sup>248</sup> See, e.g., Goldberg, supra note 239, at 53 ("This renders the FCA an extremely blunt instrument with which to remedy research fraud."). There are additional concerns that under the new HHS regulations published May 17, 2005, which require institutions to investigate allegations of research misconduct and report these results to ORI, which may follow up with FCA actions, it may become easier for FCA suits to be brought. *See, e.g.*, Memorandum from ReedSmith to Health Care Clients, Research Misconduct: A New Area of Focus for Government Enforcement, *available at* http://www.reedsmith.com/\_db/\_documents/hc0506.pdf (May 27, 2005).

<sup>249</sup> See Goldberg, supra note 239, at 57-58.

<sup>250</sup> Often the government does not want to actually go to trial and uses the threat of large damages to force defendants to settle. *See id.* 

<sup>251</sup> Burk, *supra* note 165, at 324-25.

<sup>252</sup> There are currently no HHS regulations that deal with bad faith allegations of science misconduct.

<sup>253</sup> See Hoke, supra note 247, at 5. The FCA brings with it a risk of significant financial repercussion for universities hosting scientists involved in misconduct with the whistleblowers receiving substantial percentages. There have been cases where whistleblowers have received hundreds of thousands of dollars. *Id.* 

<sup>&</sup>lt;sup>247</sup> False Claims Act, 31 U.S.C. § 3729 (2006). The act was originally passed in 1863 to punish unscrupulous Union Army suppliers and is still used primarily in the world of defense contracts. Franklin Hoke, *A Novel Application of Federal Law to Scientific Fraud Worries Universities and Reinvigorates Whistleblowers*, Scientist, Sept. 4, 1995, at 4.

damages awarded, allowing for treble damages.<sup>254</sup> Under the *qui tam* or "bounty hunter" provisions of the Act, a plaintiff can receive no less than 15% and up to 30% of the damages award or settlement.<sup>255</sup> Reasonable lawyers' fees are also recoverable. The award structure may, perversely, incentivize whistleblowers to let the meter run on fraudulent activity, so as to rack up more damages, even in the face of large social costs resulting from the misconduct. Scientists generally are against misconduct being policed under the FCA, particularly due to significant concerns that the FCA will be abused or misused.<sup>256</sup> Under the FCA, things that may not be classified within the scientific community as misconduct may still be the basis for a lawsuit. For example, communal norms in science would dictate that one look the other way when grant applicants include work that has already been done in their applications. While this sort

Moreover, many claims of fraudulent activity in science are not simple, black or white cases, and often this uncertainty can be attributed to poor record keeping. Under the FCA even poor record keeping or regulatory violations,<sup>258</sup> themselves not fraudulent science, could be actionable violations. The FCA's low bar of proof further aggravates these concerns: only a preponderance of the evidence is required. This is in contrast to most other instances of civil fraud, where the clear, unequivocal, and convincing evidence standard has been imposed.<sup>259</sup>

of 'leapfrogging' is typical behavior within the community, it may be found, under the

There are additional fears that as cases become more publicized, every disgruntled lab employee will come forward as a relator. The chilling effect resulting from the possibility that anyone and everyone in a lab is a potential plaintiff will harm the basic level of collegiality and trust that assists in scientific innovation. With even minor mistakes having the potential to be a large windfall for a relator, there will be significant efforts in time and money to make sure that no one in the lab has the opportunity to become disgruntled. The incorporation of the FCA will also result in wasted

<sup>256</sup> Keith D. Barber et al., *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 Ind. Health L. Rev. 131, 135 (2004) ("Recent developments in the use of the FCA reveal that it may be fertile ground for abuse by private whistleblowers and the government.").

<sup>257</sup> Burk, *supra* note 165, at 326.

FCA, to be a false statement.<sup>257</sup>

<sup>258</sup> See, e.g., Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1046-47 (N.D. Ill. 1998).

<sup>259</sup> See Woodby v. INS, 385 U.S. 276, 285 n.18 (1966) (citing 9 Wigmore, Evidence §2498 (3d ed. 1940)).

<sup>&</sup>lt;sup>254</sup> See False Claims Act, 31 U.S.C. §3729 (2006).

<sup>&</sup>lt;sup>255</sup> Hoke, *supra* note 247, at 4-5. The university of Alabama and one other institution recently paid over three million dollars in FCA related penalties. *Id.* 

administrative resources, both in the lab and within the institution as a whole,<sup>260</sup> to make sure that the books are perfect and unimpeachable.

Costs associated with an FCA action are huge, particularly given the relatively low level of misconduct that can trigger an FCA suit.<sup>261</sup> Moreover, in addition to the preventative costs, there could be massive costs in document review and other legal fees that researchers and academic institutions would have to shoulder.

In terms of social costs, a researcher's career could be ruined if the cases move too quickly without adequate peer review, even if the misconduct was only clerical.<sup>262</sup> Additionally, the whistle-blowing function of the FCA undermines scientific integrity by shifting an internally motivated scientific duty, to make sure that scientific knowledge is factually correct and without error, to an "externally motivated pecuniary opportunity."<sup>263</sup>

Fortunately, scientists probably do not have to be too worried about the government bringing FCA cases against them. The FCA is primarily designed to be remedial - to remedy the loss to the public - and not a punitive measure against fraud.<sup>264</sup> When the government's losses to scientific fraud are minimal, as if often the case, FCA actions would seem arbitrary and unnecessary, and as such, would be avoided.<sup>265</sup> The government would have little to gain financially, even with damages trebled.<sup>266</sup>

<sup>261</sup> Costs to the plaintiff have actually decreased. *See* Todd B. Castleton, Comment, *Compounding Fraud: The Costs of Acquiring Relator Information Under the False Claims Act and the 1993 Amendments to Federal Rules of Civil Procedure*, 4 Geo. Mason L. Rev. 327, 327 (1996) ("[T]he1993 Rules Amendments [revising rules 11 and 26 of the Federal Rules of Civil Procedure] increase the incentives for relators to bring a qui tam suit by decreasing the cost of filing qui tam suits.").

<sup>262</sup> See Stankovic, supra note 95, at 1001.. But see Goldberg, supra note 239, at 47-53 (amount of recovery may dwarf the actual fiscal costs to society).

<sup>263</sup> Dan L. Burk, *False Claims Act Can Hamper Science with 'Bounty Hunter' Lawsuits*, Scientist, Sept. 4, 1995, at 12.

<sup>264</sup> Goldberg, *supra* note 239, at 51-52 ("[T]he legal maxim of *cessante ratione legis, cessat et ipsa lex* is relevant—when the rationale for the law ends, the law ends.")

<sup>265</sup> *Id.* at 52-53.

<sup>266</sup> *Id.* at 57-58.

<sup>&</sup>lt;sup>260</sup> Vicarious liability is a significant risk for the institutions, even if the institution is unaware. See Grand Union Co. v. United States, 696 F.2d 888, 891 (11th Cir. 1983). Institutions should also be concerned about counterclaims by laid off employees who have been accused through the FCA of misconduct. See, e.g., Angelides v. Baylor Coll. of Med., 117 F.3d 833, 835 (5th Cir. 1997); Rex Dalton, Neuroscientist Accused of Misconduct Turns on His Accusers, 392 Nature 424, 424 (1998).

Thus, although civil FCA sanctions may be appropriate in the context of defense contracting, <sup>267</sup> it would seem that they are not easily applied to misconduct in science. <sup>268</sup>

#### c. Criminal Sanctions

As opposed to civil law that is ideally, but often is not,<sup>269</sup> inherently compensatory, criminal law is punitive in its nature. But, given the historical outcomes of civil actions against suspected fraudulent scientists, and the lack of any restitution to the state or the public, one could arguably suggest that all scientific misconduct cases are inherently punitive and ought not to be judged under the civil system.

Here, the concern with punitive civil actions is that they expose the defendant to similar consequences as a criminal trial, but without the concomitant constitutional procedures: "As civil law becomes more punitive, serious doubt arises about whether conventional civil procedure is suited for an unconventional civil law."<sup>270</sup> With this in mind, it may be more helpful for the scientist accused of scientific misconduct to be accused in a criminal, rather than a civil, setting. The possible outcomes are essentially the same, but the criminal setting provides greater benefits to the accused. Despite those who suggest that "the criminal law would be invoked only when necessary to maintain a public threat of severe punishment for those who cause the most harm in the most blameworthy circumstances,"<sup>271</sup> past instances of judging scientific misconduct would suggest that scientists would be more likely to see a fair result in a criminal court.

Civil sanctions should be limited to instances where the regulated behavior has some degree of positive social utility, but should, nevertheless, be allowed to internalize negative externalities by means of large damages.<sup>272</sup> Criminal penalties, however, are necessary for conduct which has no social utility and where society wants to deprive the

<sup>269</sup>See, e.g., United States v. Halper, 490 U.S. 435, 449-50 (1989) (stating that the government sought overly and overly punitive sanctions during civil action). Note also that more administrative agencies are looking towards criminalizing the willful violation of their rules. See John C. Coffee, Jr., Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law, 71 B.U. L. Rev. 193, 216 (1991) ("Since the mid-1980s, American law has experienced a little noticed explosion in the use of public welfare offenses. By one estimate, there are over 300,000 federal regulations that may be enforced criminally.").

<sup>270</sup> Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 Yale L.J. 1795, 1798 (1992).

<sup>271</sup> *Id.* at 1861.

<sup>272</sup> John C. Coffee, Jr., *Paradigms Lost: The Blurring of the Criminal and Civil Law Models --* and What Can Be Done about It, 101 Yale L.J. 1875, 1876, 1882-83 (1992).

<sup>&</sup>lt;sup>267</sup> The FCA was originally developed to respond to fraud in defense contracting. Hoke, *supra* note 247, at 5.

<sup>&</sup>lt;sup>268</sup> Stankovic, *supra* note 95, at 1009.

accused of any gains derived from his actions, as would be the case with most but not all instances of scientific misconduct.<sup>273</sup>

Criminal sanctions may not always fit the needs and requirements of the scientific community. Civil penalties are optimal in instances where society wants primarily to force defendants to internalize the social costs of their actions, here the costs to the scientific community, with a focus on the harm caused by the fraud, and less on imputing blame, particularly for the lesser tiers of science fraud.<sup>274</sup> Further, civil penalties are best imposed in situations where society wants to reduce, but not eradicate, the offending actions. By contrast, criminal penalties strive to deter all criminalized actions. But, as stated earlier, there are instances where fraudulent actions might be helpful for science.<sup>275</sup>

Civil sanctions are "preferable when society wishes to reduce the level of an activity, but does not feel able to define the precise standard of behavior it wants."<sup>276</sup> Criminal sanctions are better suited for instances where society can "precisely articulate the desired standard of conduct."<sup>277</sup> Given the difficulty in articulating a clear line between beneficial and harmful fraudulent actions, civil sanctions may thus be more appropriate.

Of further practical concern is the fact that criminal penalties are typically legislative in origin. These sorts of rules tend to be more dated and less adaptable to changes on the ground. Civil penalties, on the other hand, are more flexible in their applicability and capable of changing given varied circumstances, although this ability to quickly change does create difficulties in providing fair notice.<sup>278</sup> Still, the Supreme Court has "expressed greater tolerance of [vague] enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe."<sup>279</sup>

Without a clear idea of what the boundaries of current science misconduct are, scientists will always be concerned that they could be held liable for some sort of unknown or newly determined fraudulent action. Such fear could produce a significant chilling effect, particularly on cutting edge research. This concern is mitigated by institutions retaining the practical ability to direct the outcomes of investigations, notwithstanding the Office of Research Integrity's efforts to standardize how such

<sup>274</sup> *Id.* at 1878.

<sup>277</sup> Id.

<sup>278</sup> *Id.* at 1881 n.23 ("[T]he principle of fair notice was chiefly intended to permit ordinary citizens to be able to arrange their affairs so as to avoid entanglement with the criminal law (or presumably with other forms of extreme penalties).").

<sup>279</sup> Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99 (1982).

<sup>&</sup>lt;sup>273</sup> *Id.* at 1876.

<sup>&</sup>lt;sup>275</sup> See supra text accompanying notes 90-92.

<sup>&</sup>lt;sup>276</sup> Coffee, *supra* note 272, at 1886.

investigations are conducted. <sup>280</sup> Professor Coffee notes that if society were to criminalize deviations from a norm of ethical behavior within a professional group, the logical result would be for the groups to self-insure against criminal penalties by lowering their ethical standards.<sup>281</sup>

Criminalizing scientific misconduct would also result in the higher administrative costs associated with criminal trials and involve lay juries that might not be the optimal peers to effectively judge misconduct.

The ideal, then, would be some hybrid form of civil and criminal penalties for scientific misconduct, taking the flexibility and informality of a civil action, but merging it with the procedural safeguards of a criminal trial. Unfortunately, Professor Coffee believes that the Supreme Court is unlikely to take the country in general, or the scientific community in particular, in such a direction.<sup>282</sup> Ironically, given the extreme social and professional costs to all the scientists involved in suspected misconduct, the best route would be to forgo civil actions and embrace the procedural controls of a criminal trial, albeit while incorporating as many positive aspects of the civil system as possible.

Criminal actions can and have been brought for applied and clinical research activities. These indictments can be justified, and the scientific context should not obscure the fact that criminal activity has occurred, activity that could corrupt the grant award process, or that could be mistakenly relied upon for future research or government decision making.<sup>283</sup>

"[C]riminalization [of science misconduct] could benefit scientists and the public by strengthening support for scientific research and increasing confidence in the products of the research industry."<sup>284</sup> Criminal sanctions might be appropriate in some instances where the costs to society from fraud are very large. Such costs would include, for instance, the chilling of some areas of research tainted by prior instances of fraud, <sup>285</sup> human harm or death resulting from a treatment that is based on fraudulent research, and the additional burden on researchers who have to sift through both legitimate and illegitimate research.<sup>286</sup> While there is no law that punishes science misconduct per se,

<sup>282</sup> *Id.* at 1891.

<sup>283</sup> Stankovic, *supra* note 95, at 1004.

<sup>285</sup> Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. Mich. J.L. Reform 357, 408-09 (1992).

<sup>286</sup> *Id.* at 392-94.

<sup>&</sup>lt;sup>280</sup> Office of Res. Integrity, U.S. Dep't of Health & Hum. Servs., Sample Policy and Procedures for Responding to Allegations of Research Misconduct (2007) *available at* http://ori.dhhs.gov/policies/documents/SamplePolicyandProcedures-5-07.pdf.

<sup>&</sup>lt;sup>281</sup> Coffee, *supra* note 272, at 1879.

<sup>&</sup>lt;sup>284</sup> Sovacool, *supra* note 12 (noting that criminalization reduced the severity and frequency of misconduct, e.g. the FBI has found that since the criminalization of hate crimes, hate crimes have fallen drastically).

there are many tangential federal criminal sanctions that can be applied to those who commit fraud in science, including mail fraud, wire fraud, the federal conspiracy statute, and other statutes that punish false statements and false claims.<sup>287</sup> Even given all these criminal options, until recently, there were few, if any, scientists that had gone to prison for scientific fraud.<sup>288</sup>

Mail fraud, which makes it criminal to obtain "money or property by means of fraudulent pretenses, representations, or promises,"<sup>289</sup> encompasses even half-truths and attempts to conceal material facts with the intent to defraud.<sup>290</sup> Thus, false reporting (mailing) of facts can be considered mail fraud. Mail fraud, unlike many of the other potential criminal sanctions that can be applied against scientists, is not exclusive to research funded by government agencies.<sup>291</sup>

There are reasons, however, to not use many of the current criminal sanctions for science fraud. The False Statement statute encompasses even statements that were not made specifically to the government. "[It] does not require that the false statement must actually have been submitted to a department or agency of the United States, but rather that it was contemplated that the statement was to be utilized in a matter which was within the jurisdiction of such department or agency."<sup>292</sup> This particular legislative act should not be applicable to scientific research because defrauding the government (a requirement for culpability) should be determined based on the general morality of society, not on a morality specific to science.

<sup>288</sup> Jeneen Interlandi, An Unwelcome Discovery, N.Y. Times Mag., Oct. 22, 2006, at 98, 100.

<sup>289</sup> 18 U.S.C. §1341 (2006).

<sup>290</sup> Christopher Q. Cutler, *McNally Revisited: The "Misrepresentation Branch" of the Mail Fraud Statute a Decade Later*, 13 BYU J. Pub. L. 77, 82 n.32 (1998).

2009

<sup>&</sup>lt;sup>287</sup> Stankovic, *supra* note 95, at 977-79; *see also* Press Release, Office of Res. Integrity, U.S. Dept. of Health & Hum. Servs., Dr. Eric T. Poehlman (Mar. 17, 2005), http://ori.dhhs.gov/misconduct/cases/press\_release\_poehlman.shtml (listing claims against Dr. Eric T. Poehlman, a former tenured research professor at the University of Vermont (UVM) College of Medicine in Burlington, Vermont).

<sup>&</sup>lt;sup>291</sup> While mail fraud requires the prosecutor to prove the specific intent of the scientist to defraud the victim, this burden can be "established by circumstantial evidence and by inferences from the facts and circumstances surrounding the scheme." Jessica Shannon Schepler, *Prosecuting Child Support Frauds: A Novel Application of the Federal Mail Fraud Statute to the Willful Avoidance of Child Support*, 51 Baylor L. Rev. 581, 588 (1999). Additionally, intent does not hinge on a showing of personal benefit and can be established by proving that the defendant intended to "cause actual or potential loss to victims of fraud, whether to enrich himself, another, or no one." *Id.* 

<sup>&</sup>lt;sup>292</sup> United States v. Candella, 487 F.2d 1223, 1227 (2d Cir. 1973).

Additionally, it may be more difficult to prosecute a university professor who may not stand to gain anything monetarily from her research. A jury might find that "a person of this group who engages in research misconduct is simply not a criminal."<sup>293</sup>

## d. Novel Criminal Sanctions

Ms. Kuzma, a Deputy Pardon Attorney for the United States Department of Justice, argues that the deterrence and condemnation values of a criminal penalty far outweigh the unpleasantness of criminalizing research fraud.<sup>294</sup> But with the inherent problems relating to the usage of the off-the-shelf criminal code in prosecuting scientific fraud, some have suggested that a criminal code be specifically designed for those who commit science fraud.<sup>295</sup> Under a criminal code, the accused scientist has guaranteed rights including, due process, the right to an attorney, the right to confront the accuser and the witnesses, and the presumption of innocence attached to a high burden of proof.

Ms. Kuzma, among others, suggests that a criminal statute aimed specifically at scientific fraud can be designed with the methodology of science in mind. Such a law would include a recantation defense, and would require a relatively high level of *mens rea*, thus potentially limiting any aforementioned chilling effects.<sup>296</sup>

Those in favor of criminalizing research fraud note that with the present size and scope of biomedical research in the United States,<sup>297</sup> it would be nearly impossible for the national scientific community to police itself or to enforce its norms. The scientific establishment does not have the resources to go after every individual case of fraud, and would eventually allow many instances of misconduct to go overlooked, or be lost, within the huge research system. It is too hard for the honest scientist to keep track of all the dishonest ones; the science community would likely benefit from looking elsewhere for help in policing and enforcing its ethos.

With this backdrop in mind, a criminal code could be formulated to hold scientists liable for offenses that compromise the public's trust or the integrity of science. It might include offenses that are regularly ignored in the present regime. Actions such as misrepresentation of results, cooking data, failing to report negative results, and failing to report conflicts of interest, while small and typically negligible on an individual basis, have an aggregate effect of undermining the scientific enterprise. The law could be multitiered, having both misdemeanor and felony provisions, depending on the level of fraud and the cost of that fraud to society.

<sup>295</sup> *Id.* at 414.

<sup>296</sup> *Id.* at 415-18.

<sup>297</sup> See, e.g., Shamoo & Dunigan, *supra* note 20, at 205 (suggesting that there are around 1 million scientists in the United States with an additional 1.5 million people employed as support staff).

<sup>&</sup>lt;sup>293</sup> See Stankovic, supra note 95, at 1003.

<sup>&</sup>lt;sup>294</sup> Kuzma, *supra* note 292, at 357.

2009

It is unclear whether such a law should be vague or highly accurate. On the one hand, as mentioned earlier, vague laws tend to promote a chilling of research given the fear of unpredictable reprisals.<sup>298</sup> "Words which are vague and fluid . . . may be as much of a trap for the innocent as the ancient laws of Caligula."<sup>299</sup> "A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory applications."<sup>300</sup> This applies particularly in a context such as this one, where free speech may be restricted; "[b]road prophylactic rules in the area of free expression are suspect. Precision of regulation must be the touchstone in an area so closely touching our most precious freedoms."<sup>301</sup>

On the other hand, laws are often made intentionally vague in order to accommodate the changing and broadening reality that is necessary in the fast paced world of scientific research: it is nearly "impossible to predict and list all the unethical actions that might warrant agency action."<sup>302</sup> "Conduct such as tampering with other scientists' experiments, serious exploitation of subordinates, misuse of confidential information obtained during the grant proposal review process, or misrepresentation of authorship, could, if sufficiently serious, [eventually] be considered misconduct in science. Yet, such actions do not fit within the specified categories in the [current] definition."<sup>303</sup>

The critical need for due process, a key reason for aspiring to a criminal code for scientific misconduct, may negate the use of vague statues: "vague statutes offend Due Process by failing to provide explicit standards for those who enforce them, thus allowing discriminatory and arbitrary enforcement."<sup>304</sup> The U.S. Supreme Court "has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of *mens rea.*"<sup>305</sup> Laws that assess criminal liability for scientific misconduct must be understood by the scientists that they apply to, because the intent of the defendant is a key part of the analysis.

<sup>301</sup> NAACP v. Button, 371 U.S. 415, 438 (1963).

<sup>302</sup> James J. Dooley & Helen M. Kerch, PNNL 102044, Research Misconduct and the Physical Sciences 5 (1998) (Report prepared for the U.S. Dep't of Energy).

<sup>303</sup> Horace Freeland Judson, *The Difficult Interface: Relations between the Science and the Law*, 50 Advances in Genetics 483, 498 (2003).

<sup>304</sup> Parker v. Levy, 417 U.S. 733, 775 (1974).

<sup>305</sup> Colautti v. Franklin, 439 U.S. 379, 395 (1979).

<sup>&</sup>lt;sup>298</sup> See Nisan Steinberg, Regulation of Science Misconduct in Federally Funded Research, 10 S Cal Interdis. L J. 39, 104 (2000).

<sup>&</sup>lt;sup>299</sup> United States v. Cardiff, 344 U.S. 174, 176 (1952).

<sup>&</sup>lt;sup>300</sup> Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982).

But vagueness and due process – two potentially important components of a scientific misconduct criminal code - may be able to coexist. For example, in Parker v. Levy,<sup>306</sup> the defendant argued that both Articles 133 and Articles 143 of the Uniform Code of Military Justice describing offenses for instances "unbecoming an officer and a gentleman," and "to the prejudice of good order and discipline in the armed forces,"<sup>307</sup> were "void for vagueness" under the Due Process Clause of the Fifth Amendment. Similar to the situation with scientific misconduct, the problem of vagueness in the *Parker* case was exacerbated by the degree to which the law could impinge on First Amendment speech rights. The Parker court noted that these - vagueness and First Amendment – were valid concerns. Citing *Smith v. Goguen*,<sup>308</sup> the court reiterated that the void for vagueness doctrine "incorporates notions of fair notice or warning, [requiring] legislatures to set reasonably clear guidelines for law enforcement officials and triers of fact in order to prevent 'arbitrary and discriminatory enforcement.""<sup>309</sup> The Supreme Court also noted that it has "repeatedly recognized that the dangers inherent in vague statutes are magnified where laws touch upon First Amendment freedoms.... In such areas, more precise statutory specificity is required, lest cautious citizens steer clear of protected conduct in order to be certain of not violating the law."<sup>310</sup> But the court nevertheless curbed these concerns, finding that "the strong presumptive validity that attaches to an Act of Congress has led this Court to hold many times that statutes are not automatically invalidated as vague simply because difficulty is found in determining whether certain marginal offenses fall within their language" and that "[v]oid for vagueness simply means that criminal responsibility should not attach where one could not reasonably understand that his contemplated conduct is proscribed."<sup>311</sup> In science. just as in the military, this outcome (that individuals would not understand what conduct is statutorily proscribed) is unlikely, particularly with efforts to educate both communities on their codes of ethics.

While the Court spends some time differentiating the Military Code of Justice from the civilian code in defending its ruling, one could see how the scientific community could be analogized to the military one, supporting the expansion of this ruling to the scientific community as well. Just as the military requires that its varied regulation apply to a much larger segment of the activities of its tightly knit community, so too in science, a code ought to apply to the relatively tightly knit scientific community for a broader array of activities and conduct "that in civilian life is not subject to criminal

<sup>308</sup> Smith v. Goguen, 415 U.S. 566, 572-73 (1974).

<sup>310</sup> Parker, 417 U.S. at 775 (Stewart, J. dissenting).

<sup>311</sup> *Id.* at 757.

<sup>&</sup>lt;sup>306</sup> Parker, 417 U.S. at 752.

<sup>&</sup>lt;sup>307</sup> See 10 U.S.C. §§933, 934 (2006).

<sup>&</sup>lt;sup>309</sup> Parker v. Levy, 417 U.S. 733, 752 (1974) (quoting Smith v. Goguen, 415 U.S. 566, 572-73 (1974)).

penalties."<sup>312</sup> And like the military, scientists are often told of the ethical rules that will apply to their work, instead of relying on a doctrine that everyone ought to know the ethical guidelines intuitively.<sup>313</sup>

# i. Evidentiary Standard

In a case involving fraudulent charities, the Supreme Court recently ruled that the government shoulders the burden to prove fraud when there is a possibility that speech may be protected.<sup>314</sup> Potential scientific fraud, particularly when it involves taxpayer funded research, would similarly be defrauding the public. But the current burden of proof in scientific misconduct cases is a low civil standard of the preponderance of the evidence.<sup>315</sup> Installing a criminal code for scientific misconduct would also result in an increased burden of proof, a much-needed standard given the career-ending implications of being found guilty of scientific misconduct.

Constitutionally, the courts may be forced to implement a higher burden of proof independent of either a criminal or civil action against a scientist. Under the equal protection clause, those similarly situated should not be treated differently unless the disparity is justified. An administrative agency reviewing a case of scientific misconduct needs to provide a legitimate rational reason, one that is not palpably arbitrary or erroneous beyond rational doubt, <sup>316</sup> for discriminating between academics who currently find themselves up against a preponderance of the evidence standard and other professionals who typically need to defend themselves against a much higher clear and convincing burden of proof. <sup>317</sup> And while some might argue that the clear and convincing evidence standard is only necessary when revoking or suspending the license of a professional, the court could differentiate between licensed professionals who have satisfied extensive educational and training requirements and pass a rigorous state-

<sup>312</sup> *Id.* at 749.

<sup>313</sup> Similarly, the legal community, where the ABA Code of Professional Responsibility is similarly vague in the requirement that a lawyer ought not engage in any conduct that "adversely reflects on his fitness to practice law," may also be analogized to the military situation. Model Code of Prof'l Responsibility DR 1-102 (1983).

<sup>314</sup> Ilinois ex rel. Madigan v. Telemarketing Assocs., 538 U.S. 600, 621 n.9 (2003) ("[T]o avoid chilling protected speech, the government must bear the burden of proving that the speech it seeks to prohibit is unprotected.... The government shoulders that burden in a fraud action.").

<sup>315</sup> Public Health Service Policies on Research Misconduct, 42 CFR §93.106 (2008).

<sup>316</sup> See Kenneally v. Med. Bd., 32 Cal. Rptr. 2d 504, 510 (Cal. Ct. App. 1994).

<sup>317</sup> In re Medrano, 956 F.2d 101, 102 (5th Cir. 1992) (noting that the Supreme Court has defined the clear and convincing standard as proof that "produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable the fact finder to come to a clear conviction, without hesitancy, of the truth of the precise facts"); see also Cruzan v. Dir. of Mo. Dep't of Health, 497 U.S. 261, 285-86 n. 11 (1990).

#### ii. First Amendment Issues

While at first glance First Amendment protected academic freedom would seem to provide cover for even fraudulent research, making it constitutionally difficult to construct a scientific misconduct criminal code <sup>320</sup> ("Academic writing explaining . . . scientific work . . . is speech of the most protected kind" <sup>321</sup>), the courts have seen fit to constrain even this purportedly<sup>322</sup> protected speech.<sup>323</sup> Case law seems to limit First

<sup>319</sup> "[W]e have held that due process places a heightened burden of proof on the State in civil proceedings in which the 'individual interests at stake . . . are both 'particularly important' and 'more substantial than mere loss of money.'" *Cooper v. Oklahoma*, 517 U.S. 348, 363 (1996); *see also Woodby v. INS*, 385 U.S. 276, 285 (1966).

<sup>320</sup> Note that while writing about experiments comes under the rubric of the First Amendment, it remains debatable whether the same can be said for the actual experiments. *See* Gary Francione, *Experimentation and the Marketplace Theory of the First Amendment*, 136 U. Pa. L. Rev. 417, 419 (1987); Dana Irwin, *Freedom of Thought: The First Amendment and the Scientific Method*, 2005 Wis. L. Rev 1479, 1480 (2005); Roy Spece Jr., & Jennifer Weinzierl, *First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature*, 8 S. Cal. Interdis. L. J. 158, 158 (1998).

<sup>321</sup> Steinberg, *supra* note 298, at 88; *see also* Baltimore, *supra* note 3, at 293-297.

<sup>322</sup> See J. Peter Byrne, Academic Freedom: A "Special Concern of the First Amendment," 99 Yale L.J. 251, 252-53 (1989).

The First Amendment protects academic freedom. This simple proposition stands explicit or implicit in numerous judicial opinions, often proclaimed in fervid rhetoric. Attempts to understand the scope and foundation of a constitutional guarantee of academic freedom, however, generally result in paradox or confusion. The cases, shorn of panegyrics, are inconclusive, the promise of their rhetoric reproached by the ambiguous realities of academic life. The problems are fundamental: There has been no adequate analysis of what academic freedom the Constitution protects or of why it protects it. Lacking definition or guiding principle, the doctrine floats in the law, picking up decisions as a hull does barnacles.

<sup>323</sup> *Clark v. Holmes*, 474 F.2d 928, 931 (7th Cir. 1972), *cert. denied*, 411 U.S. 972 (1973) ("But we do not conceive academic freedom to be a license for uncontrolled expression at variance with established curricular contents and internally destructive of the proper functioning

<sup>&</sup>lt;sup>318</sup> See Mann v. Dep't of Motor Vehicles, 90 Cal. Rptr. 2d 277, 282 (Cal. Ct. App. 1999).

Nevertheless, while academics engaged in misconduct would not be protected under the rubric of academic freedom, one might argue that their speech would be otherwise protected as any other civilian. If so, government actions against scientific research need to be very narrowly tailored and the government's interest in promoting good science has to be compelling enough to suppress First Amendment rights. It could be argued that, given science's ability to police itself, and to eventually flush out much of the fraud that goes on, the government's interests are not compelling enough to constitutionally create such a law.<sup>325</sup>

To avoid these issues, this paper argues that First Amendment rights should not encompass false statements. This assertion, while seemingly obvious, is non-trivial, as the courts have not seemed to come to any clear decision on the matter. Typically, the courts, in discussing false statements, are referring to slanderous or libelous statements, <sup>326</sup> which are included in the archetypal list of speech not covered by the First Amendment: libelous speech, <sup>327</sup> fighting words, <sup>328</sup> incitement to riot, <sup>329</sup> obscenity, <sup>330</sup> and child

of the institution."); see also Stastny v. Bd. of Trustees of Cent. Wash. Univ., 647 P.2d 496, 504 (Wash. Ct. App. 1982), cert. denied, 460 U.S. 1071 (1983).

Academic freedom is not a license for activity at variance with job related procedures and requirements, nor does it encompass activities which are internally destructive to the proper function of the university or disruptive to the education process. . . . Academic freedom does not mean freedom from academic responsibility to students, colleagues and the orderly administration of the university.

Stastny, 647 P.2d at 504.

<sup>324</sup> "[S]ociety recognizes that the freedom of scientific inquiry is not an absolute right and scientists are expected to conduct their research according to widely held ethical principles." Nat'l Bioethics Advisory Comm'n, Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission 6 (1997).

<sup>325</sup> See Steinberg, supra note 298, at 104.

<sup>326</sup> E.g., Bose Corp. v. Consumers Union of U.S., Inc., 466 U.S. 485, 503-05 (1984) (holding that the defendant could not be held liable in a suit for public product disparagement, because the defendant did not make his false statements about the plaintiff's speaker system with "actual malice").

<sup>327</sup> See Beauharnais v. Illinois, 343 U.S. 250, 266 (1952).

<sup>328</sup> See Chaplinsky v. New Hampshire, 315 U.S. 568, 573 (1942).

<sup>329</sup> See Brandenburg v. Ohio, 395 U.S. 444, 447 (1969).

pornography.<sup>331</sup> Nowhere, however, does this oft-repeated list include pure false statements that do not have repercussions for any particular person.

The court in *Gertz v. Robert Welch*<sup>332</sup> may have come the closest to limiting First Amendment protection for false statements. The court noted that while "there is no such thing as a false idea,"<sup>333</sup> there is also no blanket protection for all false statements of fact. Further, even though there is no such thing as a false idea, false statements couched in terms of an opinion or idea are still not protected: "[e]xpression of opinion not honestly entertained is a factual misrepresentation."<sup>334</sup>

Still, even the *Gertz* court acknowledged that there was some protection for false statements. Although citing *New York Times Co. v. Sullivan*<sup>335</sup> and *Chaplinsky v. New Hampshire*<sup>336</sup> to support that proposition that "there is no constitutional value in false statements of fact [as they] belong to that category of utterances which 'are no essential part of any exposition of ideas, and are of such slight social value as a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality,"<sup>337</sup> the court nevertheless found that "[t]he First Amendment requires that we protect some falsehood in order to protect speech that matters."<sup>338</sup> This provides a sort of breathing space.<sup>339</sup> The Court reaffirmed this position protecting some false statements in *Herbert v. Lando*<sup>340</sup> and in *Rubin v. Coors Brewing Co.*<sup>341</sup>

<sup>330</sup> See Roth v. United States, 354 U.S. 476, 485 (1957).

<sup>331</sup> See New York v. Ferber, 458 U.S. 747, 763 (1982).

<sup>332</sup> Gertz v. Robert Welch, Inc., 418 U.S. 323, 339 (1974).

<sup>333</sup> *Id.* ("However pernicious an opinion may seem, we depend for its correction not on the conscience of judges and juries but on the competition of other ideas.").

<sup>334</sup> United States v. Konstantakakos, 121 F. App'x. 902, 905 (2d Cir. 2005).

<sup>335</sup> N.Y. Times Co. v. Sullivan, 376 U.S. 254, 270 (1964).

<sup>336</sup> Chaplinsky v. New Hampshire, 315 U.S. 568, 572 (1942).

<sup>337</sup> Gertz, 418 U.S. at 340 (citing Chaplinsky, 315 U.S. at 572).

<sup>338</sup> *Id.* at 341.

<sup>339</sup> BE&K Constr. Co. v. NLRB, 536 U.S. 516, 531 (2002).

<sup>340</sup> Herbert v. Lando, 441 U.S. 153, 171-72 (1979).

<sup>341</sup> *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 495 (1995) (Stevens, J., concurring) ("[S]ome false and misleading statements are entitled to First Amendment protection in the political realm.").

2009

Although some courts have read the Supreme Court's opinions to limit this breathing space to non-commercial speech<sup>342</sup> or only those instances where the false statement is not knowingly or recklessly made, <sup>343</sup> others are unwilling to create any *per se* rule regarding First Amendment protection of false statements. <sup>344</sup> Arguably, scientific misconduct and its concomitant false statements could be closely analogized to the Court's decision to limit First Amendment protection for false commercial statements: "[t]he truth of commercial speech . . . may be more easily verifiable by its disseminator than . . . news reporting or political commentary, in that ordinarily the advertiser seeks to disseminate information about a specific product or service that he himself provides and presumably knows more about than anyone else."<sup>345</sup> Moreover, like commercial speech, scientific speech is hardier: "[s]ince advertising is the *sine qua non* of commercial profits, there is little likelihood of its being chilled by proper regulation and forgone entirely."<sup>346</sup> Publishing is the *sine qua non* of most academic scientists and will probably not be chilled enough by the lack of First Amendment protection to be seriously damaged.

<sup>343</sup> See Hadad v. Croucher, 970 F. Supp. 1227, 1242 (N.D. Ohio 1997) ("The Supreme Court in *Pickering* declined to extend protection to false statements that are knowingly or recklessly made."); see also Garrison v. Louisiana, 379 U.S. 64, 75 (1964).

The use of calculated falsehood, however, would put a different cast on the constitutional question. Although honest utterance, even if inaccurate, may further the fruitful exercise of the right of free speech, it does not follow that the lie, knowingly and deliberately published about a public official, should enjoy a like immunity. . . . Hence the knowingly false statement and the false statement made with reckless disregard of the truth, do not enjoy constitutional protection.

*Garrison*, 379 U.S. at 75; *see also Marinello v. Bushby*, No. 1:95cv167-D-D, 1996 WL 671410, at \*10 (N.D. Miss. Nov. 1, 1996) ("It is well established law that, subject to some limitations, false statements are not entitled to First Amendment protection. Even in its narrowest application, the knowingly false statement and the false statement made with reckless disregard of the truth do not enjoy constitutional protection.") (citations omitted).

<sup>344</sup> Ceballos v. Garcetti, 361 F.3d 1168, 1179 (9th Cir. 2004) ("[S]uch statements 'are not per se unprotected by the First Amendment when they substantially relate to matters of public concern.") (quoting Johnson v. Multnomah County, Or., 48 F.3d 420, 424 (1995)), rev'd, 547 U.S. 410 (2006).

<sup>345</sup> Kasky v. Nike, Inc., 27 45 P.3d 243, 252 (2002) (quoting Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 772 n.24 (1976)); see also 44 Liquormart v. Rhode Island, 517 U.S. 484, 499 (1996) (Stevens, J., plurality opinion); Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 760 (1985) (Powell, J., plurality opinion); Bose Corp. v. Consumers Union, Inc., 466 U.S. 485, 504 n.22 (1984).

<sup>346</sup> Va. State Bd. of Pharmacy, 425 U.S. at 772 n.24.

<sup>&</sup>lt;sup>342</sup> See Edenfield v. Fane, 507 U.S. 761, 768 (1993); Zauderer v. Office of Disciplinary Counsel of Sup.e Ct. of Oh., 471 U.S. 626, 638 (1985); In re R.M.J., 455 U.S. 191, 203 (1982); Bates v. State Bar of Ariz., 433 U.S. 350, 383 (1977).

Further, at least one court has suggested that "the First Amendment does not protect false statements of fact that are part of a course of criminal conduct."<sup>347</sup> Although somewhat circular, if would seem than that if scientific misconduct were to be criminalized, First Amendment protection would not apply to false statements made by those involved in the misconduct.

In addition to the First Amendment concern, other constitutional issues include the scope of the government's ability to collect notebooks and other lab records for use in a misconduct investigation. Under most federal grants, the grantor retains the right to all the data and "anything related thereto," which broadly defined could mean any record of any result in the lab.<sup>348</sup> Under Fourth Amendment search and seizure protections, the ability of funding agencies and/or university administrators to go in and collect all of the lab's documentation may be more constrained than is currently practiced.<sup>349</sup>

#### iii. Access to Information on Exonerated Scientists

A further concern is the public availability of information, through the Freedom of Information Act, regarding scientific misconduct in cases where the allegedly fraudulent scientist was exonerated. The primary purpose of the Freedom of Information Act ("FOIA")<sup>350</sup>, which provides generally for disclosure of agency records and information, is to "open[] administrative processes to the scrutiny of the press and general public,"<sup>351</sup>and "to pierce the veil of administrative secrecy and open agency action to the light of public scrutiny."<sup>352</sup> The Act provides a number of exemptions to access to information; Exemptions 6 and 7(c) in particular, after a balancing of public and privacy interests, may limit availability of information in instances where the disclosure "could reasonably be expected to constitute an unwarranted invasion of personal privacy."<sup>353</sup>

<sup>350</sup> 5 U.S.C. §552 (2006).

<sup>351</sup> Renegotiation Bd. v. Bannercraft Clothing Co., 415 US 1, 17 (1974).

<sup>&</sup>lt;sup>347</sup> United States v. Stewart, No. 03 CR 717 (MGC), 2004 WL 113506, at \*2 (S.D.N.Y. Jan. 26, 2004); see also United States v. Chan, No. 94 CR 150 (PKL), 1995 WL 29460, at \*1 (S.D.N.Y. Jan. 26, 1995) ("[T]he First Amendment does not protect consciously false statements made in furtherance of a criminal fraud.").

<sup>&</sup>lt;sup>348</sup> Roy G. Spece, Jr. & John J. Marchalonis, *supra* note 181, at 574.

<sup>&</sup>lt;sup>349</sup> *Id.* at 618 (noting that *Schowengerdt v. Gen. Dynamics Corp.*, 823 F.2d 1328, 1337-38 (9th Cir. 1987) would find a constitutionally relevant government action even in internal private university investigations into fraud).

<sup>&</sup>lt;sup>352</sup> Wis. Project On Nuclear Arms Control v. U.S. Dep't of Commerce, 317 F.3d 275, 279 (D.C. Cir. 2003) (quoting Dep't of the Air Force v. Rose, 425 U.S. 352, 361 (1976)).

<sup>&</sup>lt;sup>353</sup> 5 U.S.C. §552 (b)(6), (b)(7)(C) (2006).

Given the potential for damage to a scientist's career even in instances of exoneration,<sup>354</sup> courts should not allow for grants of access to information regarding exonerated scientists. Notwithstanding the fact that information "relating to business judgments and relationships" does not qualify for an exemption of FOIA,<sup>355</sup> and that, arguably, scientists who have applied for publicly funded grants have already surrendered their privacy; the position advocated here has strong precedent.<sup>356</sup> For example, the D.C. Circuit has held that FOIA requests to the Patent and Trademark Office for information identifying attorneys, who had been targets of misconduct investigations but against whom charges were dismissed, are exempted under Exemption 7(c).<sup>357</sup> Whatever form future government investigations of misconduct take, they should be subject to the same FOIA exemptions.

#### IV. CONCLUSIONS

If we do not police ourselves, others may step in to do so. The result could be a scientific enterprise that is increasingly constrained by legal strictures, financial oversight, and bureaucratic provisions. We must recognize that good science resembles art more than it resembles the law, accounting, or government. If scientific research is beset with paperwork and regulation, much of the joy and creativity in doing science could disappear . . . imped[ing] scientific progress [and making] our field much less attractive to the dedicated and talented young researchers who represent the future. <sup>358</sup>

The general population has a growing mistrust of scientists in general, and often of their aims, ideologies, and research. In order to regain this trust, there need to be stronger ethical controls put in place in the scientific community. While some have suggested that the scientific community should focus on preventing inhumane uses of their research, this author feels that misconduct and fraud in science, a more important and potentially more relevant issue, must be dealt with first. Communicating directly with the public seems to be difficult for most scientists, so it is suggested that the scientific

<sup>356</sup> See McCutchen v. U.S. Dep't of Health & Hum. Servs., 30 F.3d 183, 198 (D.C. Cir. 1994) (holding that privacy interests of exonerated scientists greatly outweigh "negligible" public interest in disclosure).

<sup>357</sup> See Carter v. U.S. Dep't of Commerce, 830 F.2d 388, 394-95 (D.C. Cir. 1987).

<sup>358</sup> Alberts & Shine, *supra* note 18, at 1661.

<sup>&</sup>lt;sup>354</sup> See, e.g., Lurie v. Dep't of the Army, 970 F. Supp. 19, 37 (D.D.C. 1997) ("[T]he mere mention of an individual's name in a law enforcement file will engender comment and speculation and carries a stigmatizing connotation." (quoting *Fitzgibbon v. C.I.A.*, 911 F.2d 755, 767 (D.C. Cir. 1990)).

<sup>&</sup>lt;sup>355</sup> Wash. Post Co. v. U.S. Dep't of Justice, 863 F.2d 96, 100-01 (D.C. Cir. 1988).

community use some sort of public display to show that it acknowledges the public's concerns. A publicly sworn oath might accomplish this.<sup>359</sup> But, while an oath may raise some, albeit minimal, awareness within the scientific community, it would probably do little to prevent the underlying moral issues that have become a growing concern.<sup>360</sup> Scientists, like everyone else, respond much better to concrete actions and to reward and punishment provisions.

While scientists ought to be punished for their misconduct, it is integral that the punishment fit the crime to minimize any chilling effects on research. To this end, it is important to distinguish scientific fraud from fraudulent activity in other professions: science fraud is usually motivated more by social pressures than monetary gains, and as such it might seem inappropriate, particularly to the scientists, that science fraud be dealt with using the exact same techniques and institutions as clearly money driven forms of fraud.<sup>361</sup>

Prevention ought to include well-designed courses on ethics that will be required early and continuously throughout a researcher's career. Mentors should be encouraged and reminded by their institutions and granting agencies of the importance of creating a strong role model.<sup>362</sup> Scientific societies and funding agencies must promote talks and conferences on issues relating to fraud in science. Additionally, they can perform random and arbitrary, but confidential and private, data audits, akin to financial audits, as a method to constantly scan the system for fraud, and to act as an extra disincentive to commit fraud.<sup>363</sup>

Both the type and the method of punishment are important in this regard. Heavy civil and criminal penalties seem to be extreme and wasteful in most instances.<sup>364</sup>

<sup>360</sup> See, e.g., David Graham, *Revisiting Hippocrates: Does an Oath Really Matter?*, 284 JAMA 2841, 2842 (2000) ("[M]any modern oaths have a bland, generalized air of 'best wishes' about them, being near-meaningless formalities devoid of any influence on how medicine is truly practiced.").

<sup>361</sup> Goldberg, *supra* note 239, at 50.

<sup>362</sup> See, e.g., Frankel, *supra* note 17, at 219 ("[I]t is probably safe to say that some of the reported incidents of scientific misconduct on the part of junior scientists can be attributed in part to the breakdown of the mentoring process.").

<sup>363</sup> See Shamoo & Dunigan, *supra* note 20, at 209; *see also* Adil E. Shamoo, Correspondence, *Data Audit Would Reduce Unethical Behaviour*, 439 Nature 784 (2006). Shamoo and Dunigan note that such an audit ought to keep scientific methodologies in mind and should be done by peers rather than the government.

<sup>364</sup> It is also important to weigh whatever gains adhere to society by stringently punishing researchers against the obvious costs of chilling research.

<sup>&</sup>lt;sup>359</sup> See, e.g., Lila Guterman, A University's New Oath for Scientists: First, Do No Plagiarizing, Chron. of Higher Educ. News Blog (June 24, 2008), http://chronicle.com/news/article/4729/auniversitys-new-oath-for-scientists-first-do-no-plagiarizing (reporting the administration of a new Hippocratic Oath, pledging ethical research and scholarship, by the University of Toronto's Institute of Medical Science).

Optimally, after determining a universal definition of fraud that incorporates the idiosyncrasies of the scientific community, scientists will consider creating a criminal code particular to scientific misconduct and incorporating a tiered system of culpability, if for no other reason than pushing misconduct into the criminal realm will afford scientists with due process,<sup>365</sup> more appropriate levels of proof, and the proper degree of deterrence. A slow and drawn-out trial can ruin the careers of both the innocent and guilty, not to mention destroy years of productive research for all involved.<sup>366</sup>

Science, above all, has to remember Einstein's exhortation: "Many people say that it is the intellect which makes a great scientist. They are wrong: it is character."<sup>367</sup>

<sup>&</sup>lt;sup>365</sup> A chief complaint with ORI is the lack of due process. *See, e.g.*, Goldberg, *supra* note 239, at 63; Reynolds, *supra* note 19, at 816-18.

<sup>&</sup>lt;sup>366</sup> One compelling criticism of the David Baltimore scandal is the losses that were imposed on Dr. Baltimore's research while he was engulfed in the case.

<sup>&</sup>lt;sup>367</sup> Albert Einstein. *See, e.g.*, Bruce Alberts, President, Nat'l Acad. of Sci., Harnessing Science for a More Rational World, Address at the National Academy of Science's 140th Annual Meeting, at 7 (Apr. 28, 2003) (transcript available at http://www.nasonline.org/site/DocServer/speech2003.pdf).